Appeal No. 14-1476

United States Court of Appeals

for the

Federal Circuit

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD.,

Plaintiffs-Appellants,

– v. –

LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., MYLAN PHARMACEUTICALS INC., APOTEX INC. and APOTEX CORP.,

Defendants-Appellees,

and

WATSON LABORATORIES, INC.,

Defendant.

Appeal from the United States District Court for the Eastern District of Virginia in case no. 13-CV-0121, Judge Arenda L. Wright Allen.

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September 25, 2014

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for Defendant-Appellee certifies that:

1. The full name of every party represented by the undersigned counsel in this case is: Mylan Pharmaceuticals Inc.

2. The name of the real parties in interest represented by the undersigned counsel is: Mylan Pharmaceuticals Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by the undersigned counsel are: Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc. Mylan Inc. is a publicly held corporation and no parent corporation or publicly held corporation owns 10% or more of its stock.

4. The names of the law firms and the partners and associates that have appeared for Defendant-Appellee in the District Court or are expected to appear for Defendant-Appellee in this Court are: Robert W. McFarland of McGuire Woods LLP, Norfolk, VA; Douglas H. Carsten, Joshua Mack , Elham F. Steiner, Wendy L. Devine, and Peter Soo Kang of Wilson Sonsini Goodrich & Rosati, San Diego, CA; T.O. Kong of Wilson Sonsini Goodrich &Rosati, San Francisco, CA; Nancy Zhang of Wilson Sonsini Goodrich & Rosati, Palo Alto, CA.

September 25, 2014

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TABLE OF CONTENTS

Page

STATEMENT OF RELATED CASES 1

JURISDICTIONAL STATEMENT 1

COUNTER-STATEMENT OF THE ISSUES 2

COUNTER-STATEMENT OF THE CASE 3

I. PROSECUTION OF THE APPLICATIONS LEADING TO THE '068 PATENT 5

A. The '594 Application 5

B. The '629 Application 5

C. The PCT Application 6

D. The '113 Application 6

II. THE RESTRICTION REQUIREMENT IN THE '594 APPLICATION WAS UNRELATED TO PFIZER'S PROSECUTION OF APPLICATIONS LEADING TO THE '068 PATENT 8

III. PFIZER'S PATENTS BENEFIT FROM THE NEW MATTER 11

IV. THIS COURT INVALIDATED THE '068 PATENT FOR OBVIOUSNESS-TYPE DOUBLE PATENTING 12

V. PFIZER USED CORRECTABLE "ERRORS" TO REISSUE THE '068 PATENT AND THEN MADE CHANGES THAT ARE NOT CORRECTABLE UNDER § 251 13

VI. THE DISTRICT COURT INVALIDATED THE RE'048 PATENT 17

SUMMARY OF THE ARGUMENT 19

THE RE'048 PATENT IS AN INVALID REISSUE 19

THE RE'048 PATENT IS INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING....21

ARGUMENT....22

I. THE STANDARD OF REVIEW....22

II. THE DISTRICT COURT CORRECTLY CONCLUDED THAT THE RE'048 PATENT IS AN INVALID REISSUE....23

A. Pfizer's Alleged "Error" Is Not Correctable by Reissue....23

1. Pfizer's Failure to File a Divisional Application Is Not Correctable....25

2. Pfizer's Strategic Choice to File CIP Applications Is Not Correctable....33

3. Pfizer Cannot Use a Correctable "Error" to Make Changes Unrelated to That "Error"....44

B. The RE'048 Patent Is Invalid Because it Contains New Matter....47

1. New Compounds Remain in the RE'048 Patent....48

2. The New Compounds Are Invalidating New Matter....51

III. THE DISTRICT COURT CORRECTLY INVALIDATED THE RE'048 PATENT FOR OBVIOUSNESS-TYPE DOUBLE PATENTING....52

A. The RE'048 Patent Did Not Issue From a "Divisional" Application and Does Not Meet the Copendency Requirement....54

B. The RE'048 Patent Was Not "Filed as a Result of" a Restriction Requirement....56

CONCLUSION....58

TABLE OF AUTHORITIES

Page(s)

CASES

Adv. Tech. Incubator, Inc. v. Sharp Corp., Case No. 2:07-CV-468, 2009 WL4670942 (E.D. Tex. Sept. 18, 2009).....47

Amgen Inc. v. F. Hoffman-La Roche Ltd., 580 F.3d 1340 (Fed. Cir. 2009).....53, 55

Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986).....23

Brenner v. State of Israel, 400 F.2d 789 (D.C. Cir. 1968).....40

Celotex Corp. v. Catrett, 477 U.S. 317 (1986).....22

Cordance Corp. v. Amazon.com, Inc., Civil Action No. 06-491-MPT, 2009 WL 2252556 (D. Del. July 28, 2009).....50

Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955 (Fed. Cir. 2001).....53

Ex parte Granados, No. 2002-2030, 2003 WL 25283825 (B.P.A.I. Sept. 26, 2003).....42

Fargo Elecs., Inc. v. Iris, Ltd., 287 F. App'x 96 (Fed. Cir. 2008).....51

Fontijn v. Okamoto, 518 F.2d 610 (C.C.P.A. 1975).....40

Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373 (Fed. Cir. 2003).....53

Group One, Ltd. v. Hallmarks Cards, Inc., 407 F.3d 1297 (Fed. Cir. 2005).....49, 50

Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556 (Fed. Cir. 1989).....23

In re Byers, 230 F.2d 451 (C.C.P.A. 1956).....33

In re Clark, 522 F.2d 623 (C.C.P.A. 1975) (Rich, J.).....35, 36, 39, 40

In re Dinsmore,
757 F.3d 1343 (Fed. Cir. 2014) 23, 24, 33, 36, 45

In re Doyle,
293 F.3d 1355 (Fed. Cir. 2002) 25, 28, 29, 32

In re Hay,
534 F.2d 917 (C.C.P.A. 1976).....47, 51

In re Mead,
581 F.2d 251 (C.C.P.A. 1978).....33, 34, 35, 38, 39

In re Orita,
550 F.2d 1277 (C.C.P.A. 1977).....*Passim*

In re Serenkin,
479 F.3d 1359 (Fed. Cir. 2007) 23, 33, 34, 43, 45

In re Wadlinger,
496 F.2d 1200 (C.C.P.A. 1974).....33, 42, 43

In re Watkinson,
900 F.2d 230 (Fed. Cir. 1990) 25, 26, 27, 31

In re Weiler,
790 F.2d 1576 (Fed. Cir. 1986) 23, 25, 27, 33, 39

LG Elecs., Inc. v. Quanta Computer USA Inc., No. 07-cv-361-bbc,
2008 WL 4613054 (W.D. Wis. Mar. 4, 2008) 49

M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.,
439 F.3d 1335 (Fed. Cir. 2006) 23

Microsoft Corp. v. i4i Ltd. P'ship,
131 S. Ct. 2238 (2011).....23

Moist Cold Refrigerator Co. v. Lou Johnson, Co.,
217 F.2d 39 (9th Cir. 1954) 40, 41, 42

Nat'l Elec. Contractors Ass'n v. Nat'l Constructors Ass'n,
678 F.2d 492 (4th Cir. 1982) 37

Novo Indus., LP v. Micro Molds Corp.,
350 F.3d 1348 (Fed. Cir. 2003) 49, 50

Pfizer Inc. v. Teva Pharm. USA, Inc.,
482 F. Supp. 2d 390 (D.N.J. 2007).....12

Pfizer, Inc. v. Teva Pharm. USA, Inc.,
518 F.3d 1353 (Fed. Cir. 2008) .....*passim*

Pfizer Inc. v. Teva Pharmaceuticals USA Inc.,
86 U.S.P.Q.2d 1001 (Fed. Cir. 2008) 13

Rohm & Haas Co. v. Roberts Chemicals,
245 F.2d 693 (4th Cir. 1957) 40, 41, 42

Schering Corp. v. Amgen Inc.,
222 F.3d 1347 (Fed. Cir. 2000) 51, 52

Schering Corp. v. Mylan Pharm. Inc., Civil Action No. 09-6383
(JLL), 2012 WL 1473329 (D.N.J. Apr. 27, 2012) 46

Scott v. Harris,
550 U.S. 372 (2007).....37

Vais Arms, Inc. v. Vais,
383 F.3d 287 (5th Cir. 2004) 37

Vinewood Capital, LLC v. Dar Al-Maal Al-Islami Trust,
541 F. App'x 443 (5th Cir. 2013).....36, 37

STATUTES

28 U.S.C. § 1295(a)(1).....1

35 U.S.C. § 121 .....*passim*

35 U.S.C. § 251 .....*passim*

RULES

37 C.F.R. § 1.175 .....4, 16

Fed. Cir. R. 28(b) 3

Fed. R. Civ. P 56(c).....22

MISCELLANEOUS

MPEP § 201.06 (5th Ed. Rev. 16, Mar. 1994).....5, 6, 31, 54, 55

MPEP § 201.06 (6th Ed. Rev. 2, July. 1996).....8, 54, 55

MPEP § 201.06 (8th Ed. Rev. 5, Aug. 2006) 54

MPEP § 804.01 (5th Ed. Rev. 16, Mar. 1994).....42

MPEP § 1402 (8th Ed. Rev. 9, Aug. 2012) 25

MPEP § 1411.02 (8th Ed. Rev. 9, Aug. 2012) 47, 51

MPEP § 1412.01 (8th Ed. Rev. 9, Aug. 2012) 25

MPEP § 1414 II.B (8th Ed. Rev. 9, Aug. 2012) 45, 46
MPEP § 1455 (8th Ed. Rev. 9, Aug. 2012) 48

STATEMENT OF RELATED CASES

No case is known to counsel to be pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal. The patent-at-issue in the pending appeal is a reissue of U.S. Patent No. 5,760,068, which was invalidated by this Court's decision in *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008).

JURISDICTIONAL STATEMENT

The underlying action is a patent infringement suit, and jurisdiction for the United States District Court for the Eastern District of Virginia ("the District Court") was based on 28 U.S.C. §§ 1331 & 1338(a). On May 8, 2014, the District Court entered final judgment, pursuant to Fed R. Civ. P. 54(b) and 58, of invalidity of U.S. Reissued Patent No. RE44,048 ("the RE'048 patent") in favor of Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Lupin Pharmaceuticals, Inc., and Apotex Inc. and Apotex Corp. ("Defendants"). Appellants G.D. Searle LLC and Pfizer Asia Pacific Pte. Ltd. (collectively "Pfizer") filed a notice of appeal on May 9, 2014, appealing the entry of final judgment of invalidity of the RE'048 patent in favor of Defendants. Accordingly, this Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

COUNTER-STATEMENT OF THE ISSUES

1. Whether the RE'048 patent violates the reissue statute under 35 U.S.C. § 251 where the applicant purposely filed multiple continuation-in-part applications during the prosecution of the original patent, but used a reissue application in an attempt to rewrite the prosecution history and create a divisional application that was never filed.

2. Whether the RE'048 patent is invalid for obviousness-type double patenting where the applicants failed to take advantage of the safe harbor provision under 35 U.S.C. § 121 by failing to file a copending divisional application, and electing to use continuation-in-part applications that were not filed as a result of a restriction requirement.

COUNTER-STATEMENT OF THE CASE

Pfizer's statement of the case provides an incomplete and inaccurate description of the case and facts. Mylan Pharmaceuticals Inc. ("Mylan") thus provides the counter-statement of the case below.[1]

This appeal concerns the invalidity of a single reissue patent—the RE'048 patent—which is a reissue of U.S. Patent 5,760,068 ("the '068 patent"). This Court previously invalidated the '068 patent for obviousness-type double patenting, holding that it did not qualify for the safe harbor provision under 35 U.S.C. § 121 ("Section 121") because it did not issue from a divisional application. *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1362 (Fed. Cir. 2008). In an attempt to circumvent this Court's holding and to secure an extra unwarranted 18 months of exclusivity for its Celebrex® product,[2] Pfizer instituted reissue proceedings in the United States Patent & Trademark Office ("PTO") with one goal: to create a fictional prosecution history where the '068 patent issued from a divisional application rather than a continuation-in-part ("CIP") application.

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[1] Because Pfizer combines the Statement of the Case and Statement of the Facts into a single section, Mylan provides its counter-statement in a single section. *See* Fed. Cir. R. 28(b). Further, Mylan incorporates by reference the briefs submitted by defendant-appellee Teva Pharmaceuticals USA, Inc. and defendants-appellees Lupin Pharmaceuticals, Inc., Apotex Inc., and Apotex Corp.

[2] This extra 18-month exclusivity would represent roughly $3 billion in net revenue to Pfizer out of the pockets of United States health care consumers. *See* A3581.

The PTO initially rejected Pfizer's repeated efforts to create this fictional prosecution history because Pfizer could not allege an "error" under § 251 that led to Pfizer's proposed changes. A6170. Undeterred, Pfizer searched for any "error" that would allow them to institute reissue proceedings in order to rewrite the specification of the '068 patent. A5773 at 100:16-101:3. Ultimately, Pfizer found correctable "errors" in claims it had already cancelled, and used these "errors," which it had no interest in correcting, to open the reissue process.[3] *Compare* A6118-A6122 (amending and cancelling claims 1-12 and 18 in the preliminary amendment), *with* A6190 (alleging errors in the proviso that had been removed and claims that had been cancelled). The examiner never agreed that there was a correctable "error" that allowed Pfizer to rechristen the CIP leading to the '068 patent as a divisional. Nevertheless, under the terms of 37 C.F.R. § 1.175, because Pfizer had alleged correctable "errors," the examiner allowed the remaining revisions with just a supplemental declaration. A6209.

Pfizer used the alleged "errors" as a "Trojan horse" to accomplish its original goal of creating a fictional prosecution history for the reissue patent.

[3] Indeed, Pfizer had previously asserted in litigation against Teva the same claims it later contended were indefinite during reissue. *See Pfizer*, 518 F.3d at 1356 (noting that Pfizer asserted claims 1-4 and 11-17 of the '068 patent against Teva). During litigation, Pfizer engaged an expert to testify that those claims were definite. A6077 ("I presently plan to testify and give opinions concerning . . . the asserted claims of . . . the '068 patent are definite"); A6093 ("The Amended claims of the . . . '068 patent[] are definite.").

Recognizing Pfizer's bait-and-switch, the District Court correctly invalidated the RE'048 patent because the amendments made by Pfizer are not allowed under the reissue statute, and because it is invalid for obviousness-type double patenting. A16; A19; A20.

I. PROSECUTION OF THE APPLICATIONS LEADING TO THE '068 PATENT

A. The '594 Application

Pfizer filed U.S. Patent Application No. 08/160,594 ("the '594 application") on November 30, 1993. A4257-A4375. The '594 application, which claimed compounds, pharmaceutical compositions, and methods of use, is the grandparent of the application that ultimately issued as the '068 patent. A4343-A4374; A4838.

B. The '629 Application

Pfizer filed U.S. Patent Application No. 08/223,629 ("the '629 application") as a CIP of the '594 application on April 6, 1994. A4581; A4704. Like the '594 application, Pfizer filed the '629 application with claims directed to compounds, pharmaceutical compositions, and methods of use. A4673-A4703. Pfizer added new matter into the '629 application compared to the '594 application. A4718-A4730; A4775:16-18; *see also* A4804-A4805. The '629 application could not have been designated as a divisional of the '594 application because of the new matter. Manual of Patent Examining Procedure ("MPEP") § 201.06 (5th Ed. Rev. 16, Mar. 1994); *see also* A4780:14-23; A4781:9-14.

C. The PCT Application

Pfizer then filed International Application No. PCT/US94/12720 ("the PCT application") on November 10, 1994 as a CIP of the '629 application. A5202-A5490; A5492-A5767. The PCT application claimed compounds, pharmaceutical compositions, and methods of use like the '629 application, and also contained new matter compared to the '629 application. A5395-A5486; A4781:3-8; A4838; *see also* A4805-A4806. Like the '629 application, the PCT application could not have been designated as a divisional of the '594 application because of the addition of new matter. MPEP § 201.06 (5th Ed. Rev. 16, Mar. 1994); A4781:9-14. There were no factual inaccuracies with the PCT application's claim of priority. *See* A4767:12-24; A4768:23-A4769:15; A4779:7-A4780:5. The PCT application's claim of priority has not been changed, and to this day, the PCT application claims priority to the '629 application as a CIP. A4779:7-A4780:5; A5771-A5772 at 85:22-86:1, 86:8-12; *see also* A5786 at 90 *bis*.3(a) (showing that Pfizer may no longer withdraw its claim of priority).

D. The '113 Application

The PCT application entered the U.S. national stage as U.S. Patent Application No. 08/648,113 ("the '113 application") under 35 U.S.C. § 371(a) and was given a filing date of September 6, 1996. A5788-A6002; A6004. The '113

application is a CIP of the '629 application (which is a CIP of the '594 application). A4838; A6006.

Indeed, Pfizer made this relationship clear in the October 1996 preliminary amendment to the '113 application:

> This is an application under 35 USC §371 of International Application PCT/US94/12720, with an international filing date of November 14, 1994, ***which is a continuation-in-part*** of U.S. Patent Application Serial No. 08/223,629, filed April 6, 1994, now issued as U.S. Patent No. 5,521,207, ***which is a continuation-in-part*** of U.S. Patent Application Serial No. 08/160,594, filed November 30, 1993, now issued as U.S. Patent No. 5,466,823.

A6006 (emphasis added). Despite Pfizer's clear statement that the PCT application is a CIP of the '629 application alone, Pfizer alleges that the PCT application "identified itself as a continuation-in-part of the '629 application **and** as a continuation-in-part of the earlier '594 application . . . ." Brief of Plaintiffs-Appellants G.D. Searle LLC and Pfizer Asia Pacific Pte. Ltd. ("Pfizer's Brief") at 4-5 (emphasis added). However, Pfizer ignores the express language above and Pfizer's own representation to the PTO that the PCT application was originally filed as a CIP of the '629 application alone. A6128. Thus, the PCT application, and consequently the '113 application, is a CIP of the '629 application alone.

In an April 8, 1997 Supplemental Amendment, Pfizer noted that the examiner had issued a "lack of unity rejection/restriction requirement" during a telephone conversation, and that Pfizer had elected the method of use claims.

A6743. However, it is evident that the examiner was not reiterating the restriction requirement from the '594 application here, because Pfizer noted that the claims had been amended and new claims had been added "to correspond in subject matter with the compounds allowed in" several patents, including U.S. Patent No. 5,521,207 ("the '207 patent"). *Id.* The '629 application, which resulted in the '207 patent, was never the subject of a restriction requirement. Thus, the inclusion of the '207 patent in this "lack of unity rejection/restriction requirement" shows that this was a new restriction requirement, and not a reiteration of the '594 application restriction requirement.

Like the '629 and PCT applications, the '113 application could not have been designated as a divisional of the '594 application because of the new matter added compared to the '594 application. MPEP § 201.06 (6th Ed. Rev. 2, July. 1996); *see also* A4781:9-14. There were no factual inaccuracies in Pfizer's claim to priority in the '113 application. A4767:12-24; A4768:23-A4769:15; A4779:7-A4780:5; A5770 at 46:15-23. The '113 application issued as the '068 patent on June 2, 1998. A4838-A4892.

II. THE RESTRICTION REQUIREMENT IN THE '594 APPLICATION WAS UNRELATED TO PFIZER'S PROSECUTION OF APPLICATIONS LEADING TO THE '068 PATENT

On July 12, 1994, the examiner issued a preliminary restriction requirement in the '594 application, which restricted the claims into compounds (claims 1-20),

compositions (claims 21-26), and methods of use (claims 27-37). A4440. The examiner issued the preliminary restriction requirement more than three months after Pfizer filed the '629 application as a CIP of the '594 application. A4581; A4439; A4772:20-24.

Pfizer disagreed with the examiner's restriction, and in September 1994—two months before Pfizer filed the PCT application—Pfizer traversed the restriction requirement and asked for it to be withdrawn. A4446-A4463. Pfizer also added new method of use claims not previously in the '594 application. A4452-A4461. There is no conceivable reason, and Pfizer has articulated none, why Pfizer would add new ***method*** claims in the face of an examiner's preliminary restriction requirement unless Pfizer still intended to continue the prosecution of the restricted claims in a single application rather than in a divisional application. Only after the restriction was made final, and months after the PCT application had been filed, did Pfizer finally cancel the non-elected method of treatment claims. A1675.

While Pfizer's traversal of the preliminary restriction requirement was still pending, and in a separate application track, Pfizer filed the PCT application as a CIP of the '629 application in November 1994. A5202-5204. The PCT application was unrelated to the preliminary restriction requirement in the '594 application. This is shown by the fact that the PCT application made no reference

to any such restriction, included claims to compounds and compositions, and included claims that were broader than those in the ’594 application. A5395-A5486; A4805-A4806; A4814.

Yet, in an attempt to buttress its fictional prosecution history, Pfizer now represents that the PCT application as filed “encompass[ed] **much** of the subject matter . . . that had been restricted out of the ’594 application.” Pfizer’s Brief at 5 (emphasis added). In fact, the PCT application contained broader method of treatment claims than the claims restricted from the ’594 application, precisely because of the addition of new matter. A5456-A5486; A4805-A4806; A4814. Moreover, the PCT application contained broader compound and composition claims than the claims restricted from the ’594 application. A5395-A5455; A4805-4806; A4814.

The examiner’s restriction requirement in the ’594 application was not made final until January 12, 1995. A4499-A4501. Consequently, Pfizer filed the PCT application nearly two months before the examiner made the ’594 application restriction requirement final. A5202-5204; A4501.

It is clear, however, that Pfizer knew how to file divisional applications, as evidenced by its filing of multiple divisional applications from the ’594 application after the restriction was made final. *See* A4820 at ¶ 84; *see also* A4805 at ¶ 53.

Pfizer's filing of U.S. Application No. 08/457,059 ("the '059 application") provides an illustrative example of Pfizer's divisional practice. On June 1, 1995, Pfizer filed the '059 application as a divisional application of the '594 application, claiming the pharmaceutical compositions restricted from the '594 application. A5005-A5153; A5135; A5131. The '059 application specifically referenced the '594 restriction requirement. A5153. Moreover, Pfizer filed the '059 application five months *after* the examiner made the restriction requirement final. A5007; A4501. The '059 application issued as U.S. Patent No. 5,563,165 ("the '165 patent"), which later was held to invalidate the '068 patent. *Pfizer*, 518 F.3d at 1363; A5172-A5200. Thus, the contemporaneous record indisputably shows that Pfizer knew the difference between prosecuting a CIP application and a divisional application, and made conscious, strategic decisions regarding which applications to file as divisionals and which to file as CIPs.

III. PFIZER'S PATENTS BENEFIT FROM THE NEW MATTER

Pfizer prosecuted a number of other applications that claimed priority to the PCT application, and claimed the new matter added to the PCT application. *See* A4821-A4836. For example, at least two of Pfizer's patents—U.S. Patent No. 6,413,960 ("the '960 patent") and U.S. Patent No. 6,492,411 ("the '411 patent")—claim priority to the PCT application and claim new matter added since the '594 application. *See id*. Thus, it is apparent that Pfizer is asking this Court to permit

different characterizations of the PCT application, namely as a divisional of the '594 application for purposes of the RE'048 patent, and as a CIP of the '594 application for purposes of the '960 and '411 patents.

Moreover, the patent that issued from the '629 application, the '207 patent, claims the deracoxib compound that is currently marketed by Pfizer as the animal drug Deramaxx®. A4950; A4993. The deracoxib compound was part of the new matter that was added to the '629 application when it was filed as a CIP. A4775:16-A4776:11. Thus, Pfizer is still enjoying the benefit of this added subject matter.

IV. THIS COURT INVALIDATED THE '068 PATENT FOR OBVIOUSNESS-TYPE DOUBLE PATENTING

Pfizer asserted claims 1-4 and 11-17 of the '068 patent against Teva Pharmaceuticals USA, Inc. ("Teva") in civil action no. 04-754 (JCL) (D.N.J.). A6014-A6016; A6029. The district court found the '068 patent not invalid for obviousness-type double patenting. *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 482 F. Supp. 2d 390, 477 (D.N.J. 2007). But in 2008, this Court reversed because:

> (1) Pfizer cannot claim the protection of section 121 with respect to the '068 patent because that patent did not issue on a divisional application, and (2) the asserted claims of the '068 patent are not patentably distinct from the claims of the '165 patent. Accordingly, the '068 patent is invalid for obviousness-type double patenting.

Pfizer, 518 F.3d at 1363.

V. PFIZER USED CORRECTABLE "ERRORS" TO REISSUE THE '068 PATENT AND THEN MADE CHANGES THAT ARE NOT CORRECTABLE UNDER § 251

After this Court found the '068 patent invalid, Pfizer filed U.S. Reissue Patent Application No. 12/205,319 ("the '319 application") on September 5, 2008, seeking to reissue the '068 patent. A3969; A3972-A3973. Pfizer's preliminary amendment to the '319 application requested the PTO to re-write the prosecution history of the '068 patent by: (1) completely erasing the claim of priority to the '629 application; (2) deleting the express reference to the '113 application as a CIP, and changing the reference to read that it is a divisional of the '594 application; and (3) removing a substantial amount of material from the '068 patent. A6096-A6117. Pfizer also cancelled claims 2-12 and 18, and deleted the genus and provisos in claim 1. A6118-A6122.

In the declaration used to provide the "error upon which [the] reissue is based," Pfizer stated:

> The United States Court of Appeals for the Federal Circuit in a March 7, 2008 opinion, Pfizer Inc. v. Teva Pharmaceuticals USA Inc., 86 U.S.P.Q.2d 1001 (Fed. Cir. 2008), determined that the application from which U.S. Patent No. 5,760,068 issued failed to qualify as a divisional application entitled to protection under 35 U.S.C. §121. As a result, the Federal Circuit further held that claims 1-4 and 11-17 of the patent were invalid for obviousness-type double patenting based on the issued claims of a related family member, U.S. Patent No. 5,563,165. Applicant therefore is requesting reissue of U.S. Patent No. 5,760,068 to correct those errors that prevented the application from which the patent issued from complying with the definition of a divisional application pursuant to M.P.E.P. 201.06 entitled to

> protection under 35 U.S.C. § 121 as recently enunciated by the Federal Circuit.

A6157. The examiner found that this was not a correctable "error" under § 251, and issued a non-final rejection of the '319 application on December 3, 2009. A6159-A6164. The examiner emphasized that Pfizer's reissue declaration "fail[ed] to specifically identify an error. Failure to 'timely' file a divisional application prior to issuance of [the] original patent is not correctable in reissue under 35 U.S.C. 251." A6162.

Pfizer was unable to convince the examiner that the alleged "error" was correctable, and on September 22, 2010, the examiner issued a final rejection, maintaining that the reissue declaration was defective for the exact same reason. A6170.

Realizing its original "error" was not a correctable one, Pfizer changed tactics, and combed through the '068 patent to find an "error" that would be correctable. A5773 at 100:16-101:3. Pfizer then filed a Request for Continued Examination ("RCE") of the '319 application (A6175-A6190) with a second reissue declaration stating that: (1) claims 1-5, 13-18 were indefinite; and (2) claims 2, 3, 7, 8, and 12 were improper dependent claims. A6190. However, in total stark contrast to the contents of the declaration, throughout the litigation and prosecution of the '068 patent and '319 application, Pfizer never argued that the

claims of the ’068 patent had these “errors” until this point. A5773 at 99:25-101:3; *see also* A5774 at 104:14-24. In fact, during the previous litigation against Teva, Pfizer’s expert opined that these claims were definite. A6077 (“the asserted claims of the ‘165 patent and the ‘068 patent are definite”); A6093 (“**The Amended claims of the ‘165 and ‘068 patents are definite**”).

Pfizer’s tactic succeeded, and the examiner allowed the reissue proceedings to continue in light of the RCE and second reissue declaration. A6209. But Pfizer did not revise or amend the alleged “errors” that the examiner found to be correctable. A6193. Indeed, Pfizer could not because these claims already had been cancelled. *Id*. Applying a bait-and-switch tactic, Pfizer used the alleged “errors” in the second reissue declaration to make the corrections associated with original “error” that the examiner rejected multiple times. *Compare* A6098-6117 (amending the ’068 patent specification to correct Pfizer’s original “error”), *with* A6184-A6185 (asserting in the RCE that the amendments associated with the original “error” overcome the examiner’s double patenting rejection). Engaging in revisionist history, Pfizer deleted the claim of priority to the ’629 application, deleted references to the ’113 application being a CIP, and added language claiming that the ’113 application was a divisional of the ’594 application. A6183-A6185. In addition, Pfizer deleted a substantial amount of material to the

specification–the same deletion that Pfizer sought in its original preliminary amendment filed on September 5, 2008. *Id.*

The examiner never agreed that these revisions were allowed under § 251. Nevertheless, the examiner allowed these revisions. In the examiner's view, 37 C.F.R. § 1.175 allowed revisions outside those correctable by the "error" to be made with the mere filing of a supplemental declaration stating: "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant." A6209; A6858; A6863-A6865. Yet, even after Pfizer had filed this supplemental declaration, the examiner had further misgivings and rejected the amendments as not supported by an "error" under § 251. A6863-A6865. After Pfizer filed a lengthy legal brief in the guise of a response to the Office action, the examiner relented and allowed the reissue application based on 37 C.F.R. § 1.175. A6873-A6892; A6209.

On March 5, 2013, the '319 application issued as the RE'048 patent. A6213-A6293. All the claims from the RE'048 patent are directed toward methods of treatment using celecoxib. A6293. But the RE'048 patent contains at least five compounds, Examples 153-156 and 160, which were not present in the '594 application, thereby clearing demonstrating that RE'048 could in no way have

issued from a straight divisional application of the '594 application. A4809-A4812 at ¶¶ 65-79.

VI. THE DISTRICT COURT INVALIDATED THE RE'048 PATENT

On March 12, 2013, the District Court found the RE'048 patent invalid as a matter of law for violating the reissue statute and for obviousness-type double patenting. A20.

The District Court agreed with Defendants that the failure to file a divisional is not a correctable "error" under § 251. A12-A13. The District Court rejected Pfizer's contention that once an "error" under § 251 forms a valid support for a reissue, correction of any other error is allowed. A13.

The District Court further agreed with Defendants that Pfizer intentionally decided to file the applications leading to the RE'048 patent as CIPs, and that these intentional acts were not correctable via reissue under § 251. A13-A15. The District Court highlighted that Pfizer did not dispute that it intentionally filed the applications leading to the RE'048 patent as CIPs. A14.

Because the District Court found that the applications maturing into the RE'048 patent were not divisionals, the District Court also found that Pfizer was not entitled to the § 121 safe harbor protection. A17-A18. And like this Court's 2008 decision in *Pfizer v. Teva*, the District Court held the claims of the RE'048

patent were not patentably distinct from the ’165 patent and invalidated the RE’048 patent for obviousness-type double patenting. A18-A19.

SUMMARY OF THE ARGUMENT

The District Court correctly held the RE'048 patent invalid for two separate reasons: (1) the RE'048 patent is an invalid reissue patent; and (2) the RE'048 patent is invalid for obviousness-type double patenting. This Court previously held that the predecessor to the RE'048 patent—the '068 patent—was invalid for obviousness-type double patenting. Pfizer went to great lengths to create a fictional prosecution history to overcome this Court's holding. Pfizer used an indefiniteness error as a "Trojan horse" to make amendments that are not allowed under § 251. Pfizer rewrote the face of the patent to create a fictional divisional application and attempted to revise the specification to correspond to that fiction. The fictional priority claim on the face of the RE'048 patent is contradicted by the actual prosecution history. The fictional prosecution history eliminates the deliberate choices Pfizer made during prosecution. And the specification still includes new matter. The resulting reissued patent is invalid, just like its predecessor.

THE RE'048 PATENT IS AN INVALID REISSUE

This Court should affirm the District Court's holding that the RE'048 patent is an invalid reissue for two independent reasons. First, Pfizer's failure to file a divisional application is not a correctable "error" under 35 U.S.C. § 251. Pfizer asserts that this Court's opinion invalidating the '068 patent created an "error" that

is correctable by reissue. However, Pfizer's alleged "error" merely consists of the intentional, strategic prosecution choices that Pfizer now regrets. Pfizer consciously chose to file the applications leading to the '068 patent as CIPs, not as divisionals. The contemporaneous evidence demonstrates that these applications were meant to be CIPs. In fact, the applications could not have been divisionals. Pfizer is attempting to use a reissue application to create and take the place of a divisional application that was never filed. But the case law is clear that this is not allowed.

The case law is also clear that Pfizer may not prosecute its application *de novo* to undo Pfizer's deliberate choices during prosecution. The "error" alleged by Pfizer was not the result of inadvertence, accident, or mistake. It was a deliberate action that had nothing to do with the restriction requirement that was made during the prosecution of a *different* application. And Pfizer gained a benefit from the added subject matter. While Pfizer undoubtedly regrets its deliberate choices during the prosecution of the applications leading to the '068 patent, these deliberate choices are not correctable via reissue.

Second, Pfizer impermissibly added new subject matter to the RE'048 patent. While the District Court stated it was correcting an alleged "typographical error" in the RE'048 patent that led to the inclusion of new matter, the District Court does not have the ability to correct this alleged "typographical error"

because it is not clear from the face of the patent. Moreover, even if the District Court could correct this alleged "typographical error," there would still be new matter in the RE'048 patent because the removal of a single bracket would still result in new compounds being present in the RE'048 patent.

Accordingly, the RE'048 patent is an invalid reissue.

THE RE'048 PATENT IS INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING

This Court should similarly affirm the District Court's second holding that the RE'048 patent is invalid for obviousness-type double patenting. The RE'048 patent fails to comply with three of the statutory requirements for the double patenting safe harbor—it did not issue from a divisional application, there is no copending divisional application, and none of the applications leading to the RE'048 patent were filed as a result of a restriction requirement.

When this Court invalidated the '068 patent, it held that "Pfizer cannot claim the protection of section 121 with respect to the '068 patent because that patent did not issue on a divisional application." *Pfizer*, 518 F.3d at 1363. Similarly here, the RE'048 patent did not issue from a divisional application. While Pfizer attempted to create a fictional prosecution history for the RE'048 patent, it still does not change the fact that ***none*** of the actual applications leading to the RE'048 patent are divisional applications.

Also, contrary to the safe harbor statute, ***none*** of the applications leading to the RE'048 were filed as a result of a restriction requirement. The '629 application was filed as a CIP of the '594 application more than three months before the examiner issued a preliminary restriction requirement for the '594 application. The PCT application was filed as a CIP of the '629 application while Pfizer was contesting the preliminary restriction requirement in the '594 application, and thus *before* the restriction was made final. Furthermore, neither the PCT application nor '113 application was ever characterized as a divisional. These facts are wholly inconsistent with Pfizer's made-for-this-litigation story that these applications were filed as a result of a restriction requirement. They were not. And we know Pfizer's story to be false because Pfizer's own actions demonstrate that it knew when and how to file divisional applications within this same patent family.

Thus, because the RE'048 patent is not entitled to the safe harbor under § 121, this Court should affirm the District Court's holding that the RE'048 patent is invalid for obviousness-type double patenting.

ARGUMENT

I. THE STANDARD OF REVIEW

Summary judgment may be granted where there are no genuine issues of material fact and the movant is entitled to prevail as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); Fed. R. Civ. P 56(c). A factual

dispute is material if the dispute would affect the outcome under the applicable law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-moving party. *Id.*

This Court reviews the District Court's grant of summary judgment *de novo*, reapplying the standard applicable at the District Court. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1339 (Fed. Cir. 2006). Defendants have the burden of establishing invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011).

II. THE DISTRICT COURT CORRECTLY CONCLUDED THAT THE RE'048 PATENT IS AN INVALID REISSUE

A. Pfizer's Alleged "Error" Is Not Correctable by Reissue

In order to reissue a patent under 35 U.S.C. § 251, there must be an "error" in the patent that causes the patent to be "wholly or partly inoperative or invalid." *In re Dinsmore*, 757 F.3d 1343, 1347 (Fed. Cir. 2014) (quoting 35 U.S.C. § 251). However, § 251 was not enacted "as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application." *In re Weiler*, 790 F.2d 1576, 1582 (Fed. Cir. 1986). If there is no "error" under § 251 in the original patent, the reissued patent is invalid. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1566 (Fed. Cir. 1989). Whether or not an applicant satisfied the reissue requirements of 35 U.S.C. § 251 is a matter of law. *In re Serenkin*, 479 F.3d 1359, 1361 (Fed. Cir. 2007).

This Court's recent decision in *Dinsmore* strengthens the District Court's holding that Pfizer's alleged "error" is not correctable by reissue. In *Dinsmore*, this Court found that because the applicants had not identified any "deficient understanding" that led them to file the terminal disclaimer, there was no "error" under § 251. 757 F.3d at 1348-49. This Court noted that the applicants did not allege: (1) that they had mistakenly believed that a terminal disclaimer was needed; (2) that they misunderstood the language of the terminal disclaimer; or (3) that they thought that the patents were commonly owned, as required by the terminal disclaimer. *Id.* at 1349. Instead, this Court found that the applicants were "ultimately seeking simply to revise a choice they made, not to remedy the result of a mistaken belief." *Id.*

Similarly here, Pfizer's alleged "error" is not correctable by reissue. Pfizer understood how to prosecute CIP applications and how to prosecute divisional applications. *See supra* Counter-Statement of the Case ("Case") §§ I.B-I.D, II. Pfizer made the strategic decision to file the applications leading to the '068 patent as CIPs in order to get the benefit of the added subject matter. *See supra* Case § III. The CIP applications leading to the '068 patent could not have been filed as divisionals and were never intended to be divisionals. *See supra* Case §§ I.B.-I.D. Pfizer's alleged "error" is a fiction designed to revise a strategic choice that Pfizer

elected to make during prosecution, and this Court should affirm the District Court's holding.

1. Pfizer's Failure to File a Divisional Application Is Not Correctable

Pfizer asserts that "[i]t is . . . clear that Pfizer's prosecution of the prior application as a continuation-in-part, rather than a divisional," was a correctable "error" under § 251. Pfizer's Brief at 23. To the contrary, it is clear that Pfizer's alleged "error" is not correctable under § 251. The District Court correctly found that failure to file a divisional application is not correctable via reissue. A12; *see In re Watkinson*, 900 F.2d 230, 231-33 (Fed. Cir. 1990); *In re Orita*, 550 F.2d 1277, 1280 (C.C.P.A. 1977); *see also In re Doyle*, 293 F.3d 1355, 1358 (Fed. Cir. 2002); *Weiler*, 790 F.2d at 1582; MPEP § 1402 (8th Ed. Rev. 9, Aug. 2012); MPEP § 1412.01 (8th Ed. Rev. 9, Aug. 2012). In fact, failure to file a divisional has never been found by this Court to be a correctable "error."

Moreover, the case law is consistent that an applicant may not use a reissue application to take the place of a divisional application that was never filed. *See Doyle*, 293 F.3d at 1356; *Watkinson*, 900 F.2d at 231-33; *Weiler*, 790 F.2d at 1582; *Orita*, 550 F.2d at 1280.

In *Orita*, in response to a restriction requirement, the applicant elected the compound and compound-preparation claims and cancelled the method of treatment claims. 550 F.2d at 1278. The applicant did not file a divisional on the

unelected method of treatment claims. *Id.* After the elected claims issued, the applicant filed a reissue application alleging that the "error" was that the applicant "had forgotten to timely file a divisional application covering the originally non-elected subject matter." *Id.* at 1278-79. The examiner rejected this purported "error" and the Board affirmed. *Id.* at 1279. On appeal, the C.C.P.A. agreed that there was no error, and found that if applicants prevailed "the copendency requirement would become meaningless, for should an applicant fail to file a divisional application while maintaining copendency as required by section 120, he could simply revert to section 251 in order to cure his mistake." *Id.* at 1280-81. Thus, the applicant in *Orita* could not use a reissue application to take the place of a divisional application that was never filed.

Similarly, in *Watkinson*, after the examiner issued a restriction requirement, the applicant allowed the elected claims to issue without filing a divisional application on the unelected claims. 900 F.2d at 231. The applicant then filed a reissue application directed to the unelected claims, asserting that the "error" was a mistaken belief that the claims were not patentable. *Id.* The examiner rejected this purported "error" and the Board affirmed. *Id.* On appeal, this Court agreed and found "that the failure to file a divisional application, regardless of the propriety of the underlying restriction requirement, is not an error correctable by reissue under 35 U.S.C. § 251." *Id.* This Court further stated that "we will not permit

[applicant] to undermine the co-pendency requirement under sections 120 and 121 by using the reissue statute to avoid a restriction requirement in which she acquiesced." *Id.* at 233 (footnote omitted). Again, the applicant in *Watkinson* could not use a reissue application to take the place of a divisional application that was never filed.

In *Weiler*, after receiving a restriction requirement, the applicant elected the claims directed to an "assay method," and these claims issued without the applicant filing any divisional applications. 790 F.2d at 1578. Later, the applicant filed a reissue application directed to subject matter that was not originally claimed and was not the subject of the restriction requirement. *Id.* at 1578-79. The examiner and the Board rejected the reissue application, finding that there was no "error" under § 251. *Id.* at 1579.

In affirming the Board, this Court stated that "[t]he reissue statute was not enacted . . . as a grant to the patentee of a second opportunity to prosecute *de novo* his original application." *Id.* at 1582. This Court further reasoned that "[t]hough Weiler *might have* filed a divisional application containing claims 13 and 19, there is nothing of record remotely indicating that Weiler or his counsel or anyone else ever thought of doing so, or ever intended doing so, or failed to do so only through error." *Id.* (emphasis in original). Thus, the applicant in *Weiler* could not use a reissue application to take the place of a divisional that was never filed.

In *Doyle*, the applicant's error was not failure to file a divisional application; instead, the applicant had a deficient understanding of the proper scope of the claims. The applicant received a nine-way restriction requirement and elected to proceed with method claims directed toward using a genus of catalysts. *Doyle*, 293 F.3d at 1356. After these claims issued, the applicant determined that the claims were narrower than they should be, and requested a reissue to cover a larger genus of catalysts. *Id.* at 1357. The proposed reissue genus read on some of the claims of the non-elected groups. *Id.* The examiner rejected the reissue, finding that the applicant had failed to identify an "error" correctable by reissue, and the Board affirmed. *Id.* at 1357-58.

On appeal, this Court characterized the issue as "whether failure to present a so-called linking claim, a claim broad enough to read on—or link—two or more groups of claims subject to a restriction requirement, is an error correctable by reissue." *Id.* at 1358. In holding that this was a correctable error, this Court reasoned that the applicant "simply seeks a broadening reissue of his [patent] to cover material that he invented and disclosed, but inadvertently failed to claim in his issued patent." *Id.* This Court distinguished *Orita*, stating that case "turned on the fact that the applicant could not have asserted the new reissue claims with the elected group," while "Dr. Doyle could have prosecuted his claims with the elected group without running afoul of the restriction requirement because they are linking

claims." *Id.* at 1360. This Court further found that because the applicant was attempting to broaden the claims, the alleged "error" fell squarely within 35 U.S.C. § 251. *Id.* Thus, the applicant's error in *Doyle* was not the failure to file a divisional application, but rather the failure to include these broader claims in the original patent. The applicant in *Doyle* was not using a reissue application to take the place of a divisional application that he failed to file.

Here, Pfizer used a reissue application to take the place of a divisional application that was never filed. Pfizer never intended to file the PCT or '113 applications as divisionals of the '594 application. *See supra* Case §§ I.C-I.D. The examiner issued the initial restriction requirement during the prosecution of the '594 application—three months after Pfizer filed the '629 application as a CIP of the '594 application. A4581; A4439; A4772:20-24. Yet, Pfizer did not immediately file divisional applications in response to the initial restriction requirement in the '594 application, but instead filed a traversal and added new method of use claims. A4446-A4463; A4452-4461. While the traversal was pending, Pfizer filed the PCT application as a CIP of the '629 application. A5202-5204. The PCT application did not contain any reference to the restriction requirement, and included compound, composition, and method of treatment claims that were broader than the claims subject to restriction in the '594 application. A5395-A5486; A4805-A4806; A4814. In fact, the restriction

requirement did not become final until two months after Pfizer filed the PCT application. A5202-5204; A4501. Similar to *Weiler*, Pfizer never intended to file the PCT or '113 applications as divisionals of the '594 application.

Moreover, Pfizer never filed a divisional application with the reissued claims. While Pfizer filed other divisional applications after the restriction requirement was made final (*see* A5007-A5153; *see also* A4820 at ¶ 84), it never filed a divisional directed to the method of treatment claims that were restricted from the '594 application. *See supra* Case §§ I.A-I.D. Pfizer's assertion that it believed a CIP was the same as a divisional application during this time lacks credibility because it is contradicted by Pfizer's own actions demonstrating that Pfizer indeed knew the difference. *See supra* Case §§ I.B-I.D, II. Pfizer's reissued patent attempts to undo Pfizer's knowing, strategic prosecution choices by erasing the '629 application and pretending that the PCT application was filed as a divisional of the '594 application.

Moreover, Pfizer's attempt to rewrite history is undermined by the fact that the PCT application remains unchanged and has additional subject matter compared to the '594 application. A4779:7–A4780:5; A4781:3-8; A4805-A4806; A4779:7-A4780:5; A5771-A5772 at 85:22-86:1, 86:8-12; *see also* A5786 at 90 *bis*.3(a). Pfizer never attempted to reopen prosecution to remove added matter from any of the CIP applications. *See* A4779:7-A4780:5; A5771-A5772 at 85:22-

86:1, 86:8-12. Pfizer has other issued patents that rely upon the material that was added to the CIP applications. *See* A4821-A4836. None of the applications leading to the '068 patent can be divisionals of the '594 application. *See* MPEP § 201.06 (5th Ed. Rev. 16, Mar. 1994).

Pfizer attempts to distinguish *Watkinson*, *Weiler*, and *Orita* by arguing that there was no copending application in those cases while there is a copending application here. *E.g.*, Pfizer's Brief at 28. Yet, it is undisputed that there was no copending *divisional* application here. The '594 application, and all the divisionals Pfizer filed off of it, issued years before Pfizer filed the reissue application. *Compare* A22, *with* A3691, *and* A3796. The PCT and '113 applications were CIPs—not divisionals—of the '629 application, which was a CIP of the '594 application. A5202-A5490; A5492-A5767; A4838; A6006. Pfizer has attempted to create a fictional divisional application and bootstrap that fiction to meet the copendency requirement. *Watkinson, Weiler*, and *Orita* all stand for the principle that an applicant may not use reissue to create a fictional divisional application in order to meet the copendency requirement. Should Pfizer prevail in its arguments, the copendency requirement would be rendered meaningless.

Here, like *Orita*, Pfizer cancelled the method of treatment claims that were restricted from the '594 application. 550 F.2d at 1278; A4446-A4463. Also like *Orita*, Pfizer did not file a divisional with the unelected method of treatment

claims. 550 F.2d at 1278. And just like in *Orita*, Pfizer could not have prosecuted the non-elected method of treatment claims in the '594 application. 550 F.2d at 1280; A4501. As stated in *Orita*, "[a]lthough appellants undoubtedly erred by failing to file a timely divisional application in order to obtain a divisional patent, it does not follow that such error caused the original patent to be" correctable under § 251. 550 F.2d at 1280.

Further, as noted in *Doyle*, a "reissue lies only for correction of error *in an existing patent.*" 293 F.3d at 1361 (emphasis in original). Here, Pfizer is not trying to correct an "error" in an *existing patent*. Pfizer has attempted to create a *fictional divisional application* by erasing the '629 application, erasing the new matter that was added to the '629 and PCT applications, and pretending that the PCT application was filed as a result of the restriction requirement. The patent that Pfizer wants to correct simply does not exist. Pfizer is attempting to use reissue to fabricate a divisional application that was never filed. *See Doyle*, 293 F.3d at 1362 (finding that the alleged error in *Orita* was "merely an error pertaining to the prosecution (or lack thereof) of other, divisional applications directed towards the nonelected groups."). This is not an "error" that is correctable under § 251. This Court should affirm the District Court's holding.

2. Pfizer's Strategic Choice to File CIP Applications Is Not Correctable

Only errors that are the result of inadvertence, accident, or mistake are correctable by reissue. *E.g.*, *In re Wadlinger*, 496 F.2d 1200, 1207 (C.C.P.A. 1974); *In re Byers*, 230 F.2d 451, 457 (C.C.P.A. 1956). "Error" under § 251 does not include intentional, deliberate actions made during patent prosecution without a deficient understanding leading to the "error." *See Dinsmore*, 757 F.3d at 1348-49; *Serenkin*, 479 F.3d at 1365; *In re Mead*, 581 F.2d 251, 257 (C.C.P.A. 1978); *see also Weiler*, 790 F.2d at 1583 n.4 ("As indicated in the text § 251 does not authorize a patentee to re-present his application."); *Byers*, 230 F.2d at 455 (holding that the deliberate amendment of a claim to secure a patent is not an error). As noted *supra*, a deficient understanding of a choice during prosecution can lead to an "error," but a mere error in judgment is not correctable under § 251. *Dinsmore*, 757 F.3d at 1348-49.

In *Serenkin*, the applicant's intentional, deliberate actions during prosecution did not result in a correctable "error" under § 251. The applicant in *Serenkin* made the intentional choice to include drawings and receive a later filing date for a patent application, rather than to proceed with an application without the drawings in order to get an earlier filing date. 479 F.3d at 1360-61. Later, the applicant regretted this intentional prosecution choice and filed a reissue application in an attempt to gain the benefit of the earlier filing date. *Id.* at 1361. The examiner

rejected the reissue application, and the Board affirmed the rejection, finding that the applicant "failed to obtain the benefit of the earlier filing date, not because of inadvertence, accident, or mistake, which are correctable by reissue under § 251, but because of a deliberate choice, which it construed as an error of judgment." *Id.*

This Court affirmed, noting that the applicant relied on hindsight for its argument that the alleged "error" was failing to accept the earlier filing date without the drawings. *Id.* at 1361-62. This Court further noted that "the deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under § 251." *Id.* at 1362. This Court concluded that because the applicant made the deliberate choice to give up the filing date so that certain material could be included with the application, it was not a correctable error under § 251. *Id.* at 1365.

In *Mead*, the applicant allowed an application to issue as a patent, and planned to file a later application to obtain claims directed to the claims at issue. 581 F.2d at 253 n.4. However, after discovering intervening prior art, the applicant filed a reissue application directed to the claims at issue. *Id.* The applicant alleged that the "error" was "a mistake about the state of the art, in that neither the applicant nor his counsel were aware of the [intervening prior art reference], the existence of which was highly detrimental to the course of action then being pursued." *Id.* The examiner and the Board found that the alleged "error" was not

correctable under § 251 because "the subject matter of the appealed claims was never intended to be claimed in the original patent but rather in a subsequent application . . . ." *Id.* at 254.

The C.C.P.A. affirmed, finding that the applicant "made a conscious choice not to file a continuing application claiming the appealed subject matter [] during copendency with the application . . . ." *Id*. at 256. Although the C.C.P.A. acknowledged that the applicant was not aware of the intervening reference when the application was allowed to issue as a patent, the court found that this was not an "error" under § 251. *Id.* at 257. While the applicant undoubtedly regretted the decision to allow the application to issue as a patent without claims directed to the claims at issue, because it was a deliberate decision (and part of a plan to claim the matter in a later application), it was not an "error" under § 251.

In *Clark*, the applicant sought reissue of a patent that had been invalidated by the Fifth Circuit. *In re Clark*, 522 F.2d 623, 623-24 (C.C.P.A. 1975) (Rich, J.). In affirming the examiner's rejection of the reissue application, Judge Rich found that the amendments were not being made to correct an "error" under § 251, but were being made because the Fifth Circuit found the patent invalid over prior art that was not disclosed to the PTO. *Id*. at 626. Judge Rich further found that there was no "error" in failing to disclose this prior art because the evidence showed that the applicant was aware of it and recognized its relevance. *Id.* at 626-27. Again,

in *Clark*, while the applicant likely regretted the decision not to disclose the reference, there was no "error" resulting from inadvertence, accident, or mistake that led to the failure to disclose.

Here, Pfizer made deliberate choices during the prosecution of the '068 patent that it now regrets. There is no evidence that any of the deliberate choices that it made during the prosecution of the '068 patent, or related applications, were the result of inadvertence, accident, or mistake. Indeed, Pfizer admits that it could "have readily prosecuted the method-of-treatment claims restricted out of the parent '594 application in a divisional application." Pfizer's Brief at 24. Yet, Pfizer chose not to, and elected to get the benefit of added subject matter to the '629, PCT, and '113 applications. *See* A4821-A4836. Pfizer is simply attempting to revise a choice it made in exchange for the benefit of adding new matter. *See Dinsmore*, 757 F.3d at 1349.

Instead of pointing to contemporaneous evidence to show a false or deficient understanding, Pfizer cites the self-serving testimony (based on a leading question) of Pfizer's prosecuting attorney that he intended to get the benefit of the safe harbor provision. Pfizer's Brief at 24. Yet, this testimony carries little weight because it is not supported by any evidence and is contradicted by the plain language of the statute. *Compare* Pfizer's Brief at 24, *and* A7122 at 196:13-197:6, *with Vinewood Capital, LLC v. Dar Al-Maal Al-Islami Trust*, 541 F. App'x 443,

447-48 (5th Cir. 2013) ("[A] party's uncorroborated self-serving testimony cannot prevent summary judgment, particularly if the overwhelming documentary evidence supports the opposite scenario.") (citing *Vais Arms, Inc. v. Vais*, 383 F.3d 287, 294 (5th Cir. 2004)), *Nat'l Elec. Contractors Ass'n v. Nat'l Constructors Ass'n*, 678 F.2d 492, 498 (4th Cir. 1982) (holding that self-serving deposition statements were not "sufficient to create an issue of fact"), *and Scott v. Harris*, 550 U.S. 372, 380 (2007) (stating a court may reject a version of events that is "blatantly contradicted by the record . . . for purposes of ruling on a motion for summary judgment").

All the contemporaneous evidence supports the conclusion that there was no false or deficient understanding that led to Pfizer's alleged "error." Moreover, Pfizer obtained the benefit of this added subject matter, just as the applicants in *Dinsmore* obtained the benefit of overcoming the double patenting rejection and the applicant in *Serenkin* obtained the benefit of including the drawings. *See* A4821-A4836. Pfizer even admits that it gained a benefit from the addition of this new subject matter. Pfizer's Brief at 24-25 ("Because Pfizer's research had progressed . . . Pfizer prosecuted the method-of-treatment claims, together with claims to additional compounds, in the continuation-in-part application that resulted in the '068 patent."). Instead of a "false or deficient understanding,"

Pfizer's alleged error is merely a "now-regretted choice" which is not correctable under § 251.

Similar to *Serenkin*, the alleged error here is based on hindsight. Pfizer regrets filing the '629 application as a CIP, and is trying to erase this application from the prosecution history. Pfizer also regrets filing the PCT application as a CIP of the '629 application, and now wishes it had been filed as a divisional of the '594 application. Yet, as noted in *Weiler* and *Orita*, the reissue procedure is not an opportunity to prosecute an application *de novo*. But Pfizer is attempting to do exactly that.

Pfizer also now regrets not filing a divisional application on the method of treatment claims restricted from the '594 application. After it received a restriction requirement during the prosecution of the '594 application, Pfizer could have filed a divisional directed to methods of treatment, but Pfizer chose not to. Pfizer now regrets this choice and used reissue to prosecute these applications *de novo*. But Pfizer intentionally omitted filing a divisional application on the method of treatment claims, and pursued this subject matter in CIPs rather than divisionals. Such intentional acts do not constitute an "error" under § 251. *See Mead*, 581 F.2d at 257. Moreover, permitting Pfizer to rewrite the prosecution history in this way

would defeat the copendency requirement.[4] *Cf. id.* ("That intentional omission of the appealed subject matter from the original application combined with the plan to claim it in the subsequent application, does not constitute "error" under § 251 because to permit appellant to use the reissue statute in this manner would defeat the purpose behind the copendency requirement of §120 of the statute.").

While Pfizer *might have* been able to file a divisional from the '594 application containing the method of treatment claims, Pfizer did not, and there is no evidence in the record indicating that the failure to file this divisional was the result of an "error."[5] *Cf. Weiler*, 790 F.2d at 1582 ("[t]hough Weiler *might have* filed a divisional application containing claims 13 and 19, there is nothing of record remotely indicating that Weiler or his counsel or anyone else ever thought of doing so, or ever intended doing so, or failed to do so only through error.") (emphasis in original). Just like *Clark*, Pfizer's amendments to the '068 patent were not made because of an "error" under § 251; instead Pfizer's amendments

[4] As noted *supra*, Pfizer cannot show copendency here—the '629, PCT, and '113 applications were filed as CIPs not divisionals.

[5] Pfizer may argue that the examiner reiterated the restriction requirement issued for the '594 application during the '113 application. *See* A6743. However, these restriction requirements are not related, as can be seen by the fact that the compounds of the '629 application—which Pfizer acknowledges was not subject to the '594 restriction requirement—were mentioned with respect to the '113 application restriction requirement. *See supra* Case § I.D.

were made because this Court invalidated the claims of the '068 patent. *See* 522 F.2d at 626.

Pfizer further argues that it can obtain a reissue patent in order to perfect a priority claim. Pfizer's Brief at 25. However, Pfizer is attempting to rewrite the prosecution history to create a fictional divisional application, not perfect a priority claim. The cases cited by Pfizer merely stand for the proposition that an applicant can correct a factual error in a claim of priority. *See Fontijn v. Okamoto*, 518 F.2d 610, 616 (C.C.P.A. 1975) (finding "error" when patentee failed to notify PTO of earlier-filed copending applications during prosecution of original application); *Brenner v. State of Israel*, 400 F.2d 789, 790 (D.C. Cir. 1968) (finding "error" because the applicant failed to file a certified copy of the foreign application from which priority was claimed). These cases correct the claim of priority to reflect ***actual events*** during the prosecution history. However, Pfizer attempted to do the opposite– rewrite the prosecution history to reflect ***fictional events***. There are no cases holding that an applicant can create a fictional prosecution history in order to preserve the validity of a patent.

Undaunted, Pfizer relies upon *Moist Cold Refrigerator Co. v. Lou Johnson, Co.*, 217 F.2d 39 (9th Cir. 1954) and *Rohm & Haas Co. v. Roberts Chemicals*, 245 F.2d 693 (4th Cir. 1957), to argue that "reissue is proper where a patent is invalid as a misunderstanding, or even a lack of clarity, about the law." Pfizer's Brief at

25-26. But these cases provide only persuasive authority that ***actual changes in law***–as opposed to mere misunderstanding or purported lack of clarity about the law–may serve as a basis for "error" under the reissue statute. In *Moist Cold*, the Ninth Circuit held that an applicant's failure to foresee a change in case law directed to enablement qualified as an error under the reissue statute. 217 F.2d at 42. The *Moist Cold* court even highlighted the unexpected nature of the change in law by stating that the change was "a surprise to the patent bar." *Id.* The change in law was even more pronounced in *Rohm & Haas*. There, the patent statute of July 19, 1952 was passed between the time when the patent issued and the applicant sought reissue. *Rohm & Haas*, 245 F.2d at 697-99. Given the "peculiar circumstances" surrounding the case, the *Rohm & Haas* court stated that "the filing of the application for reissue at so late a date is explained by ***changes in the law*** which clarified the rights of the patentee." *Id.* at 698 (emphasis added).

No analogous change in case law or statute occurred here. Previously, this Court confirmed what 35 U.S.C. § 121 plainly and explicitly stated on its face: the safe harbor provision applies exclusively to "divisional applications." *Pfizer*, 518 F.3d at 1359-60. No binding authority at the time suggested otherwise. *Id.* at 1362. Pfizer's argument that there was a lack of clarity in the law relies on dicta instead of the plain language of the statute. *See* Pfizer's Brief at 23-24; *see Pfizer*, 518 F.3d at 1362 (stating that the issue of whether CIP applications fall within the

scope of section 121 "was not decided by those cases"). Pfizer could not have reasonably believed that filing a CIP off the '594 application three months before an initial restriction requirement would have complied with the safe harbor when such an application did not meet two of the statutory requirements. *See also Pfizer*, 518 F.3d at 1362 (citing *Ex parte Granados*, No. 2002-2030, 2003 WL 25283825, at *11 (B.P.A.I. Sept. 26, 2003) ("[T]he instant case is a continuation-in-part, not a divisional . . . . It therefore does not fall within the literal terms of [section 121].")); MPEP § 804.01 (5th Ed. Rev. 16, Mar. 1994). And Pfizer's own actions show that Pfizer did not believe this because Pfizer filed divisional applications that referenced the restriction requirement after the restriction was made final. *See* A5007-A5153; *see also* A4820 at ¶ 84; A4805 at ¶ 53.

More importantly, there is no contemporaneous evidence supporting Pfizer's assertion that it had a "deficient understanding of the law" (Pfizer's Brief at 24); instead, all of the evidence shows that Pfizer made the strategic choice to add new matter to the CIP applications in order to get the benefit of that added matter. *See supra* Case § III. Thus, both *Moist Cold* and *Rohm & Haas* are inapposite to the present case.

The *Wadlinger* case cited by Pfizer is also inapposite. Pfizer's Brief at 26. The C.C.P.A. in *Wadlinger* stated, in *dicta*, that "'mistake' has a broad sweep and is certainly inclusive of actions taken in full consciousness." *Wadlinger*, 496 F.2d

at 1207. In *Wadlinger*, the "error" at issue was the cancellation of particular method of use claims during the prosecution of the patent. *Id.* at 1202. The applicants sought a reissue application with claims similar to the cancelled claims. *Id.* However, the applicants did not dispute that a claim similar in scope to the issued claim was not available through reissue; instead, the applicants pointed to precedent to support their position that *narrower* claims than those cancelled during prosecution could be obtained via reissue. *Id.* at 1204. After a fact-intensive inquiry, the C.C.P.A. determined that the claims were narrower in scope than the claims cancelled during prosecution, and thus could be obtained through reissue. *Id.* at 1206.

The facts of *Wadlinger* are inapplicable here. As stated in *Serenkin*, "the nature of the error asserted in *Wadlinger* differs greatly from the so-called error asserted here. [Pfizer] is not attempting to obtain claims that differ in scope from claims that [it] previously cancelled. Instead, [Pfizer] is attempting to use the reissue process to undo the consequences of [its] attorney's conscious decision to" file CIP applications. 479 F.3d at 1365.

There was no omission or inadvertent error in the prosecution history of the '068 patent. There is no dispute that when the applications were filed, they were meant to be filed as CIPs, not divisionals. The intentional, deliberate actions of

Pfizer during the prosecution of the ’068 patent are not correctable by reissue. Thus, this Court should affirm the District Court’s decision.

3. Pfizer Cannot Use a Correctable “Error” to Make Changes Unrelated to That “Error”

In the alternative, Pfizer argues that it is allowed to rewrite the prosecution history of the ’068 patent because it found unrelated, correctable “errors.” Pfizer’s Brief at 39-45. This Court should reject Pfizer’s “Trojan horse” theory of reissue—allowing any changes to a patent once a single, correctable “error” has been identified—because it is not supported by the statute or case law, and would effectively eviscerate the reissue statute.

Despite Pfizer’s arguments during the prosecution of the reissue application, the examiner never accepted that Pfizer’s initial alleged “error”—failure to file the ’113 application as a divisional—was one that could be corrected by reissue. *See, e.g.*, A6159-A6164; A6167-A6173. Accordingly, the examiner issued a final rejection of the reissue application because the reissue declaration was defective. A6167-A6173.

It was not until Pfizer filed a RCE with a new declaration that the examiner allowed the reissue patent. A6175-A6190. In the new declaration, Pfizer alleged that the “errors” correctable by reissue were that claims 1-5, 13-18 were indefinite, and claims 2, 3, 7, 8, and 12 were improper dependent claims. A6190. These “errors” were accepted by the examiner, but were unrelated to whether or not a

reissue application can be used to correct failure to file a divisional.[6] *See supra* Case § V.

Notably, Pfizer cites no case law to support its theory that once one correctable "error" is found, the door is open to making changes unrelated to the correctable "error." And the reason is simple—such a rule is contrary to the case law and statute.

In a reissue application, applicants may only correct acts of inadvertence, accident, or mistake that qualify as "errors" under § 251. *See Serenkin*, 479 F.3d at 1365; *see also Orita*, 550 F.2d at 1280. While 37 C.F.R. § 1.175 allows additional changes to be made to a reissue application without further explanation, these changes still need to be "errors" under § 251. *See Dinsmore*, at 757 F.3d at 1347 ("Section 251 requires not only that the original patent be 'wholly or partly inoperative or invalid,' and that the inoperativeness or invalidity be by reason of a defective specification or drawing or unduly broad or narrow claiming, ***but that 'error' be the cause of the infirmity***.") (emphasis added); *see also* MPEP § 1414 II.B (8th Ed. Rev. 9, Aug. 2012) ("Where more than one error is specified in the oath/declaration and some of the designated 'errors' are found to not be 'errors'

[6] Pfizer was never interested in correcting these alleged "errors"; instead, Pfizer was searching for "errors" to find a way to reissue the '068 patent. A5773 at 100:16-101:3.

under 35 U.S.C. 251, *any remaining error which is an error under 35 U.S.C. 251 will still support the reissue*.") (emphasis added).

Pfizer argues that the District Court relied on *Schering Corp. v. Mylan Pharm. Inc.*, Civil Action No. 09-6383 (JLL), 2012 WL 1473329 (D.N.J. Apr. 27, 2012), "to take the position that other corrections [in a reissue application] could be made only insofar as they were 'narrowing changes to the patent's claims.'" Pfizer's Brief at 43. Pfizer misconstrues both *Schering* and the law.

First, the District Court cited to *Schering* for the proposition that "[p]atent law is not so forgiving" as to grant a patentee carte blanche to correct "any other error" "once an error under 35 U.S.C. § 251 forms a valid support for a reissue . . . ." A13. The District Court did not cite *Schering* for the proposition that an applicant is restricted to narrowing claims once a valid basis for reissue is established.

Second, the District Court correctly cited to *Schering* as precedent for the limits of what may be corrected in a reissue. *See Schering*, 2012 WL 1473329, at *15-16. Allowing a reissue applicant to correct an uncorrectable "error" simply because the applicant found a single correctable "error" in the same patent would make meaningless the "error" requirement under § 251. *Orita*, 550 F.2d at 1280-81 ("Section 251 is not a panacea designed to cure every mistake which might be committed by an applicant or his attorney . . . ."). However, this is precisely the

result Pfizer is seeking. Pfizer relies on indefiniteness "errors" in the claims (arguably correctable "errors"), to justify converting its voluntary CIP into a divisional (an uncorrectable "error").

As the District Court noted, "[t]he question in this suit is not whether reissue is permitted on another basis, but rather, whether the reissue in this case *could* be filed as a *divisional*." A13 (emphasis in original). Pfizer's attempt to use a single correctable "error" as a "Trojan horse" to rewrite its deliberate choices during the prosecution of the '068 patent should be rejected by this Court.

B. The RE'048 Patent Is Invalid Because It Contains New Matter

New matter is not allowed in a reissue application. 35 U.S.C. § 251; MPEP § 1411.02 (8th Ed. Rev. 9, Aug. 2012). The introduction of new matter into a reissue application invalidates the resulting patent. *See In re Hay*, 534 F.2d 917, 919 (C.C.P.A. 1976); *Adv. Tech. Incubator, Inc. v. Sharp Corp.*, Case No. 2:07-CV-468, 2009 WL4670942, at *4 (E.D. Tex. Sept. 18, 2009).

There is no dispute that the RE'048 patent contains new compounds not present in the original '594 application. A10. However, the District Court stated that these new compounds were the result of a "typographical error" in the form of brackets. A11. The District Court proceeded to "correct this typographical error" on its way to finding the RE'048 patent not invalid for the addition of new matter. *Id.* But the District Court erred in its holding because it did not have the authority

to remove this bracket on its own. Moreover, the removal of this single bracket did not remove all of the new matter. Accordingly, the RE'048 patent is an invalid reissue because it contains new matter.

1. New Compounds Remain in the RE'048 Patent

Brackets are used to indicate the matter to be excluded from a reissue patent. A11; MPEP § 1455 (8th Ed. Rev. 9, Aug. 2012). The arrangement of brackets in Table VII of the RE'048 patent results in the inclusion of five compounds in the RE'048 patent that were not present in the original '594 application: Examples 153-156 and 160. A10; A4809-A4812 at ¶¶ 65-79; A6427-A6429 at ¶¶ 150-155. Pfizer argued that these brackets were a "typographical error" and urged the District Court to correct.[7] A10. The District Court agreed, stating "a typographical error is obvious from the face of the '048 patent" and "[t]he prosecution history also does not contradict Plaintiffs' contention that the indicated material was supposed to be deleted." A11. But the record shows that it is not obvious from the face of the patent that these brackets are "typographical errors." Moreover, the District Court misapplied the law regarding its authority to correct patents.

[7] Within Table VII, there are three brackets that Pfizer alleges are errors: (1) a closing bracket at the end of Example 152; (2) a closing bracket at the end of Example 157; and (3) an opening bracket in the middle of Example 162. A84-A85; A10-A11.

"[T]he district court can correct an error only if the error is evident from the face of the patent." *Group One, Ltd. v. Hallmarks Cards, Inc.*, 407 F.3d 1297, 1302-03 (Fed. Cir. 2005); *see also LG Elecs., Inc. v. Quanta Computer USA Inc.*, No. 07-cv-361-bbc, 2008 WL 4613054, at *7 (W.D. Wis. Mar. 4, 2008) ("The law in this area is uncharacteristically clear: a court may correct a patent only if the error *and* its correction are obvious.") (emphasis in original). This Court has limited a district court's power to correct a patent to situations where: "(1) the correction is not subject to reasonable debate based on consideration of the claim language and specification; and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus., LP v. Micro Molds Corp.*, 350 F.3d 1348, 1356-57 (Fed. Cir. 2003).

The removal of any one of the three brackets would still result in new matter in the RE'048 patent. If the first bracket at the end of Example 152 was deleted (A85), the patent would still contain the new compound embodied in Example 160. *Id*. If the second bracket at the end of Example 157 was deleted (*id*.), all five new compounds would still remain. And if the third bracket in the middle of Example 162 was deleted (*id*.), again all five new compounds would remain. Thus, removal of any one of the three brackets would still result in new compounds in the RE'048 patent.

Moreover, removal of all three brackets would be impermissible because the erroneous nature of the brackets is not obvious from the face of the RE'048 patent. A person reading the patent would understand that these compounds were included in the RE'048 patent. There is nothing on the face of the patent to suggest that brackets at issue were improperly placed, especially since the use of brackets is extensive in the RE'048 patent.

Pfizer may point to the prosecution history as evidence of its intent to exclude these new compounds and brackets. But the case law makes clear that the District Court should only consider the prosecution history if the error is evident from the face of the patent. *E.g.*, *Group One*, 407 F.3d at 1303 (refusing to add language omitted due to "printing error" despite the fact that the "prosecution history discloses that the missing language was required to be added by the examiner as a condition for issuance" because "one cannot discern what language is missing simply by reading the patent."); *Novo*, 350 F.3d at 1357-58; *Cordance Corp. v. Amazon.com, Inc.*, Civil Action No. 06-491-MPT, 2009 WL 2252556, at *4 (D. Del. July 28, 2009) (refusing to delete the article "an" in a claim because "the changes were not clear 'typographical' errors that were apparent on the face of the patent").

Here, it is not clear from the face of the RE'048 patent which of these three brackets are "typographical errors." Indeed, even if this Court were to agree with

the District Court that a closing bracket without an opening bracket constitutes an error on the face of the patent, there is no indication that the other two brackets are "typographical errors" on the face of the patent. Thus, the District Court should not have considered the prosecution history when determining whether there was a "typographical error."[8] Accordingly, there is new matter in the RE'048 patent.

2. The New Compounds Are Invalidating New Matter

"New matter [is] matter not present in the patent sought to be reissued." MPEP § 1411.02 (8th Ed. Rev. 9, Aug. 2012). "The fundamental inquiry [to whether new matter is added] is whether the material added [] was inherently contained in the original application." *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352 (Fed. Cir. 2000); *see also Hay*, 534 F.3d at 919. Here, it is undisputed that the RE'048 patent contains compounds not present in the '594 application. A10.

[8] Even if this Court were to go beyond the face of the RE'048 patent and consider the prosecution history, it is still unclear whether the brackets at issue were errors. The three brackets Pfizer seeks to remove all appear in Pfizer's preliminary amendment to the '319 application. A6112-A6113. This suggests Pfizer intended to include the brackets in the RE'048 reissue patent, providing yet another ground for denying Pfizer's improper request. *See Fargo Elecs., Inc. v. Iris, Ltd.*, 287 F. App'x 96, 101-02 (Fed. Cir. 2008) (consulting the prosecution history to see if the alleged error was subject to more than one reasonable construction, finding that the prosecution history did not resolve the issue, and affirming that the district court could not correct the error).

Pfizer may argue that the new compounds do not constitute invalidating new matter under 35 U.S.C. § 251 because it intended for these compounds to be excluded from the RE'048 patent, and it did not claim these compounds. But the analysis to determine new matter does not consider the intent of the applicant; instead, it is whether the added material was inherently contained in the original application. *Schering*, 222 F.3d at 1352. As discussed above, it is undisputed that the RE'048 patent introduces new compounds not previously present in the '594 application. A10.

For the foregoing reasons, the RE'048 patent contains new matter and is invalid under § 251.

III. THE DISTRICT COURT CORRECTLY INVALIDATED THE RE'048 PATENT FOR OBVIOUSNESS-TYPE DOUBLE PATENTING

The RE'048 patent is not entitled to the safe harbor of 35 U.S.C. § 121, and is therefore invalid over the '165 patent. Pfizer does not dispute that the claims of the RE'048 patent are not patentably distinct from the '165 patent, and so the only issue before this Court is whether the RE'048 patent is entitled to the § 121 safe harbor.

"Obviousness-type double patenting is a judicially created doctrine that prohibits a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned

earlier patent." *Pfizer*, 518 F.3d at 1363 (internal citations and quotations omitted); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). Whether a patent is invalid for obviousness-type double patenting is a question of law. *Pfizer*, 518 F.3d at 1363.

The purpose of this "safe harbor" provision is to protect applications that were required to be divided from being used as obviousness-type double patenting references against one another. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1350 (Fed. Cir. 2009). The § 121 safe harbor, however, only applies if each of the following requirements are met: (1) the application was filed as a divisional application; (2) the application was "filed as a result of" a restriction requirement made by the examiner; (3) the application was filed "before the issuance of the patent on the other application;" and (4) the divisional application claims the subject matter restricted by the examiner. *Pfizer*, 518 F.3d at 1359-60. The party seeking to invoke the protection of the § 121 safe harbor has the burden of showing that § 121 applies to the patent at issue. *See Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003).

The RE'048 patent is not entitled to the protection of the § 121 safe harbor because the first three safe harbor requirements are not met. The RE'048 patent was not the product of a divisional application. The application that matured into the RE'048 patent was not the result of a restriction requirement. And the

application that issued as the RE'048 patent was not filed "before the issuance of the patent on the other application." Therefore, the '165 patent remains invalidating prior art to the RE'048 patent. *See Pfizer*, 518 F.3d at 1362.

A. The RE'048 Patent Did Not Issue from a "Divisional" Application and Does Not Meet the Copendency Requirement

It is undisputed that the RE'048 patent did not issue from a divisional application. *See supra* Case § I. The failure to file a divisional application is not correctable via reissue. Nothing that occurred in the reissue prosecution changes this fact. It is also undisputed that Pfizer did not intend to file divisional applications when it filed the '629, PCT, and '113 applications as CIPs. *See supra* Case §§ I.B-I.D. And Pfizer benefitted from these filings with a longer patent term and the addition of new matter. *See supra* Case § III.

Moreover, even though Pfizer claims that the RE'048 patent is the result of a divisional, there is no divisional in fact. The '113 application that matured into the '068 patent was never meant to be a divisional, and it could not have been a divisional. A6006; MPEP § 201.06 (6th Ed. Rev. 2, July 1996). Merely rewriting the specification of the '068 patent to call the '113 application a divisional application does not make it so. It is undisputed that the '629 application could not have been a divisional of the '594 application because of the new matter. *See* MPEP § 201.06 (5th Ed. Rev. 16, Mar. 1994); *see also Pfizer*, 518 F.3d at 1360 (quoting MPEP § 201.06 (8th Ed. Rev. 5, Aug. 2006)). It is undisputed that the

PCT application could not have been a divisional of the '594 application because of the new matter. *See* MPEP § 201.06 (5th Ed. Rev. 16, Mar. 1994); A4768:23-A4769:15. It is undisputed that the '113 application could not have been a divisional of the '594 application because of the new matter. A6006; MPEP § 201.06 (6th Ed. Rev. 2, July 1996). Despite the later revisions to the specification, the application that matured into the RE'048 patent was not and is not a divisional in fact. Thus, it cannot take advantage of the § 121 safe harbor. *See Amgen*, 580 F.3d at 1354 ("Because the '178 and '179 applications were filed as continuation applications instead of divisional applications, we hold that the '933, '422, and '349 patents do not receive the protections afforded by § 121's safe harbor.").

Noticeably missing from Pfizer's Brief is an identification of an application that is a divisional for the purpose of the safe harbor statute. The reason is clear: there is no such application. As explained above, the '629, PCT, and '113 applications cannot be divisionals. And the '319 application was filed after the '594 application issued, and so it cannot be the divisional for the safe harbor provision because it does not meet the copendency requirement—*i.e.*, it was not filed "before the issuance of the patent on the other application." Pfizer cannot conjure a divisional application by rewriting the prosecution history of the '068 patent to make it appear as if a divisional application was filed. A divisional

application was never filed during the prosecution of the '068 patent, and the safe harbor does not apply.

B. The RE'048 Patent Was Not "Filed as a Result of" a Restriction Requirement

The RE'048 patent is also not protected by the safe harbor because none of the applications that led to the RE'048 patent were filed as a result of a restriction requirement. The statutory language is clear–in order to take refuge in the § 121 safe harbor, an application needs to be "filed as a result of" a restriction requirement. 35 U.S.C. § 121; *see also Pfizer*, 518 F.3d at 1362 ("We conclude that the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications."). None of the applications leading to the RE'048 patent were "filed as a result of a restriction requirement."

First, the '629 application, the parent of the PCT and '113 applications, was filed *three months before* the restriction requirement. A4581; A4439; A4772:20-24. Second, the restriction requirement was not made final until *two months after* the PCT application was filed. *Compare* A5492, *with* A1675. Third, there is no reference in the PCT or '113 applications to the restriction requirement, and neither of these applications was ever characterized as "divisionals."[9] A5492; A6006.

[9] As noted above, the restriction requirement from the '594 application was not reiterated during the '113 application. *See supra* Case § I.D.

Moreover, the evidence shows that the CIP applications were never meant to be "filed as a result of a restriction requirement." Pfizer filed the PCT application after it traversed the preliminary restriction requirement. *Compare* A4446-A4463, *with* A5492. Assuming *arguendo* that the PCT application was a divisional—which it was not—if the examiner had agreed with Pfizer's traversal and withdrawn the restriction requirement, the PCT would have been considered to be a voluntary divisional and the safe harbor would not have applied. It would have been illogical for Pfizer to file a divisional application while its traversal was still under consideration, which is why Pfizer waited until after the restriction was made final to file the divisional applications that were *actually* filed as a result of the restriction requirement.

Further, Pfizer never intended the PCT application to be a divisional of the '594 application. Pfizer added new subject matter to the claims of the PCT application that broadened the scope of the PCT application. A5395-A5486; A4781:3-8; A4838; *see also* A4805-A4806. Pfizer further included claims directed to compounds and compositions, in addition to claims directed to methods of treatment. A5395-A5486; *see also* A4805-A4806. If the PCT application were meant to be a divisional directed to the method of treatment claims, the PCT application would presumably only include method claims. Similarly, if the PCT application was meant to be a divisional application of the '594 application, there

would be some mention of the '594 application restriction requirement in the PCT or '113 application, just like there was in the '059 application. A5153. But there is no mention of the restriction requirement in either the PCT or '113 application. The inescapable conclusion is that none of the applications leading to the RE'048 patent were filed "as a result of" a restriction requirement.

Therefore, the § 121 safe harbor does not apply, and the RE'048 patent is invalid for obviousness-type double patenting.

CONCLUSION

For all these reasons, Mylan respectfully requests this Court to affirm the District Court's summary judgment that the RE'048 patent is invalid as a matter of law.

September 25, 2014

Respectfully submitted,
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ADDENDUM

ADDENDUM

	Page(s)
MPEP 201.06 (5th Ed.Rev.16, Mar.1994)	ADDENDUM 1-3
MPEP 201.06 (6th Ed.Rev. 2, July 1996)	ADDENDUM 4-5
MPEP 201.06 (8th Ed.Rev.5, Aug. 2006)	ADDENDUM 6-8
MPEP 804.01 (5th Ed.Rev.16, Mar.1994)	ADDENDUM 9-10
MPEP 1402 (8th Ed.Rev.9, Aug.2012)	ADDENDUM 11-14
MPEP 1411.02 (8th Ed.Rev.9, Aug.2012)	ADDENDUM 15-16
MPEP 1412.01 (8th Ed.Rev.9, Aug.2012)	ADDENDUM 17-19
MPEP 1414 IIB (8th Ed.Rev.9, Aug. 2012)	ADDENDUM 20-24
MPEP 1455 (8th Ed.Rev.9, Aug. 2012)	ADDENDUM 25-28

Chapter 200 Types, Cross-Noting, and Status of Application

201 Types of Applications
201.01 Sole
201.02 Joint
201.03 Correction of Inventorship in an Application
201.04 Parent Application
201.04(a) Original Application
201.05 Reissue Application
201.06 Division Application
201.06(a) Division-Continuation Program
201.06(b) File Wrapper Continuing Procedure
201.07 Continuation Application
201.08 Continuation-in-Part Application
201.09 Substitute Application
201.10 Refile
201.11 Continuity Between Applications: When Entitled to Filing Date
201.11(a) Filing of Continuation or Continuation-in-part Application During Pendency of International Application Designating the United States
201.12 Assignment Carries Title
201.13 Right of Priority of Foreign Application
201.13(a) Right of Priority Based Upon an Application for an Inventor's Certificate
201.13(b) Right of Priority Based Upon an International Application Filed Under the Patent Cooperation Treaty
201.14 Right of Priority, Formal Requirements
201.14(a) Right of Priority, Time for Filing Papers
201.14(b) Right of Priority, Papers Required
201.14(c) Right of Priority, Practice
201.14(d) Proper Identification of Priority Application
201.15 Right of Priority, Overcoming a Reference
201.16 Using Certificate of Correction to Perfect Claim for Priority under 35 U.S.C. 119
202 Cross-Noting
202.01 In Specification
202.02 Notation on File Wrapper of a Divisional, Continuation, Continuation-in-Part, or Substitute Application
202.03 Notation On File Wrapper When Priority Is Claimed for Foreign Application
202.04 In Oath or Declaration
202.05 In Case of Reissues
203 Status of Applications
203.01 New
203.02 Rejected
203.03 Amended
203.04 Allowed or in Issue
203.05 Abandoned
203.06 Incomplete
203.07 Abandonment for Failure to Pay Issue Fee
203.08 Status Inquiries
203.08(a) Congressional and Other Official Inquiries

201 Types of Applications [R-15]

37 CFR 1.9 Definitions.

(a) A national application as used in this chapter means a U.S. national application for patent which was either filed in the Office under 35 U.S.C. 111 or which resulted from an international application after compliance with 35 U.S.C. 371.

(b) An international application as used in this chapter means an international application for patent filed under the Patent Cooperation Treaty prior to entering national processing at the Designated Office stage.

* * * * *

National applications (35 U.S.C. 111) vs. National Stage applications (35 U.S.C. 371)

Treatment of national applications under 35 U.S.C. 111 and national stage applications under 35 U.S.C. 371 are similar but not identical. Note the following examples:

(1) Restriction practice under MPEP § 806+ is applied to national applications under 35 U.S.C. 111 while unity of invention practice under MPEP *>Chapter 1800< is applied to national stage applications under 35 U.S.C. 371.

(2) National applications filed under 35 U.S.C. 111 without an executed oath or declaration or filing fee are governed by the notification practice set forth in 37 CFR 1.53(d) while national stage applications filed under 35 U.S.C. 371 without an oath or declaration or national stage fee must be completed **as set forth in 37 CFR 1.494 >and 1.495<.

National patent applications fall under three broad types: (1) applications for patent under 35 U.S.C. 101 relating to a "new and useful process, machine, manufacture, or composition of matter, etc."; (2) applications for plant patents under 35 U.S.C. 161; and (3) applications for design patents under 35 U.S.C. 171. The first type of patents are sometimes referred to as "utility" patents or "mechanical" patents when being contrasted with plant or design patents. The specialized procedure which pertains to the examination of applications for design and plant patents are treated in detail in Chapters 1500 and 1600, respectively. National applications include original, plant, design, reissue, divisional, and continuation applications (which may be filed under 37 CFR 1.53, 37 CFR 1.60, 37 CFR 1.62), and continuation-in-part applications (which may be filed under 37 CFR 1.53 or 37 CFR 1.62).

201.01 Sole

An application wherein the invention is presented as that of a single person is termed a sole application.

201.02 Joint [R-14]

A joint application is one in which the invention is presented as that of two or more persons. >See MPEP § 605.07.<

201.03 Correction of Inventorship in an Application [R-15]

Correction of inventorship is permitted by amendment under 35 U.S.C. 116. If at least one of the correct inventors has been named in an application but it is discovered that correction of inventorship is necessary, applicants are advised to consider abandoning the application and the filing of a continuing appli-

tion under 37 CFR 1.48(b) is deficient because [1]

Examiner Note:

1.This paragraph should only be used when the inventorship was previously correct but an inventor is being deleted because claims have been amended or canceled such that he or she is no longer an inventor of any remaining claim in the application. If the inventorship is being corrected because of an error in naming the correct inventors, use paragraph 2.13 instead of this paragraph.

Potential rejections

- A rejection under 35 U.S.C. 102(f) or (g) must be considered if the petition is denied.

- The grant or denial of the petition may result in the loss of inventorship overlap between a parent application and a continuing application and an inability to claim benefit in the continuing application of the parent applications filing date under 35 U.S.C. 120. Intervening references must then be considered.

2.Insert one or more of the following reasons in the bracket:

"the petition has not been diligently filed" (explanation required).;

"the petition lacks the statement required under 37 CFR 1.48(b)(l)";

"it lacks the required fee under 37 CFR 1.17(h)".

¶ 2.13.2 Correction of Inventorship under 37 CFR 1.48(c), Insufficient

The petition to correct the inventorship in this application under 37 CFR 1.48(c) requesting addition of an inventor(s) is deficient because [1]

Examiner Note:

See paragraph 2.13

¶ 2.14 Correction of Inventorship Sufficient

In view of the papers filed [1], it has been found that this application, as filed, through error and without any deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48. The inventorship of this application has been changed by [2].

Examiner Note:

In bracket 2, insert explanation of correction made, including addition or deletion of appropriate names.

For correction of inventorship in a patent, see 37 CFR 1.324 and MPEP § 1481.

37 CFR 1.48(b)

37 CFR 1.48(b) provides for deleting the names of persons originally properly included as inventors, but whose invention is no longer being claimed in the application. Such a situation would arise where claims have been amended or deleted because they are unpatentable or as a result of a requirement for restriction of the application to one invention, or for other reasons. A petition under 37 CFR 1.48(b) to delete an inventor would be appropriate prior to an action by the examining group where it is decided not to pursue particular aspects of an invention attributable to some of the original named inventors. However, a petition under 37 CFR 1.48(b) is not an available means to avoid execution of the application as originally filed under 37 CFR 1.53(b) situations. Public Law 98-622 and 37 CFR 1.48(b) change the result reached in *Ex parte Lyon*, 146 USPQ 222, 1965 C. D. 362 (Bd. App. 1964). 37 CFR 1.48(b) requires only a petition and fee with the petition including a statement identifying each named inventor who is being deleted and acknowledging that the inventor's invention is no longer being claimed in the application. The amendment would have to be diligently made under 37 CFR 1.48(b). The statement may be signed by applicant's registered attorney or agent who then takes full responsibility for ensuring that the inventor is not being improperly deleted from the application.

When any correction or change is effected, the file should be sent to the Application Division for revision of its records and the change should be noted on the original oath or declaration by writing in red ink in the left column "See Paper No. __ for inventorship changes". See MPEP § 605.04(g).

37 CFR 1.48(c)

37 CFR 1.48(c) provides for the situation where an application discloses unclaimed subject matter by an inventor or inventors not named in the application as filed. In such a situation, the application may be amended pursuant to 37 CFR 1.48(a) to add claims to the subject matter and also to name the correct inventors for the application. The claims would be added by an amendment and, in addition, an amendment pursuant to 37 CFR 1.48(a) would be required to correct the inventors named in the application. Any claims added to the application must be supported by the disclosure as filed and cannot add new matter.

201.04 Parent Application

The term "parent" is applied to an earlier application of an inventor disclosing a given invention. Such invention may or may not be claimed in the first application. Benefit of the filing date of copending parent application may be claimed under 35 U.S.C. 120.

201.04(a) Original Application

"Original" is used in the patent statute and rules to refer to an application which is not a reissue application. An original application may be a "first" filing or a continuing application.

201.05 Reissue Application

A reissue application is an application for a patent to take the place of an unexpired patent that is defective in some one or more particulars. A detailed treatment of reissues will be found in chapter 1400.

201.06 Division Application [R-14]

A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division". It may be filed

pursuant to 37 CFR 1.53, >37 CFR< 1.60 or >37 CFR< 1.62. Both must have at least one common applicant. The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application.

In the interest of expediting the processing of newly filed divisional applications, filed as a result of a restriction requirement, applicants are requested to include the appropriate Patent and Trademark Office classification of the divisional application and the status and location of the parent application, on the papers submitted. The appropriate classification for the divisional application may be found in the Office communication of the parent case wherein the requirement was made. It is suggested that this classification designation be placed in the upper right hand corner of the letter of transmittal accompanying these divisional applications.

Use Form Paragraph 2.01 to remind applicant of possible division status.

¶ 2.01 Definition of division

This application appears to be a division of application Serial No. [1] filed [2]. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division". The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application.

Examiner Note:

[1] In bracket 1, insert the serial No. of parent application.

[2] In bracket 2, insert the filing date of parent application.

A design application may be considered to be a division of a utility application, and is entitled to the filing date thereof if the drawings of the earlier filed utility application show the same article as that in the design application sufficiently to comply with 35 U.S.C. 112, first paragraph. However, such a divisional design application may only be filed under the procedure set forth in 37 CFR 1.53, not under 37 CFR 1.60 or >37 CFR< 1.62. See MPEP § 1504.20.

While a divisional application may depart from the phraseology used in the parent case there may be no departure therefrom in substance or variation in the disclosure that would amount to "new matter" if introduced by amendment into the parent case. Compare MPEP *§ 201.08 and >§< 201.11.

For notation to be put on the file wrapper by the examiner in the case of a divisional application see MPEP § 202.02.

201.06(a) Division-Continuation Program [R-15]

37 CFR 1.60. Continuation or divisional application for invention disclosed in a prior application

(a) [Reserved]

(b) An applicant may omit signing of the oath or declaration in a continuation or divisional application (filed under the conditions specified in 35 U.S.C. 120 or 121 and § 1.78(a)) if>:< (1) the prior application was a complete application as set forth in in § 1.51(a), (2) applicant indicates that the application is being filed pursuant to this section and files a true copy of the prior complete application as filed including the specification (*>with< claims), drawings, oath or declaration showing the signature or an indication it was signed, and any amendments referred to in the oath or declaration filed to complete the prior application, (3) the inventors named in the continuation or divisional application are the same or less than all the inventors named in the prior application, and (4) the application is filed before the patenting or abandonment of or termination of proceedings on the prior application. The copy of the prior application must be accompanied by a statement that the application papers filed are a true copy of the prior application and that no amendments referred to in the oath or declaration filed to complete the prior application introduced new matter therein. Such statement must be by the applicant or applicant's attorney or agent and must be a verified statement if made by a person not registered to practice before the Patent and Trademark Office. Only amendments reducing the number of claims or adding a reference to the prior application (§ 1.78(a)) will be entered before calculating the filing fee and granting of the filing date. If the continuation or divisional application is filed by less than all the inventors named in the prior application, a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation or divisional application. *>Except as provided in paragraph (d) of this section, if< a true copy of the prior application as filed is not filed with the application or if the statement that the application papers are a true copy is omitted, the application will not be given a filing date earlier than the date upon which the copy and statement are filed, unless a petition with the fee set forth in § 1.17(i)(1) is filed which satisfactorily explains the delay in filing these items.

(c) If an application filed pursuant to paragraph (b) of this section is incomplete >for reasons other than those specified in paragraph (d) of this secion<, applicant will be notified and given a time period within which to complete the application in order to obtain a filing date as of the date of filing the omitted item provided the omitted item is filed before patenting or abandonment of or termination of proceedings on the prior application. If the omission is not corrected within the time period set, the application will be returned or otherwise disposed of; the fee, if submitted, will be refunded less the handling fee set forth in § 1.21(n).

>(d) If an application filed pursuant to paragraph (b) of this section is otherwise complete, but does not include the appropriate filing fee or a true copy of the oath or declaration from the prior complete application, showing the signature or an indication it was signed, a filing date will be granted and applicant will be so notified and given a period of time within which to file the fee, or the true copy of the oath or declaration and to pay the surcharge as set forth in § 1.16(e) in order to prevent abandonment of the application. The notification pursuant to this paragraph may be made simultaneously with any notification pursuant to paragraph (c) of this section.<

[Paras. (b) and (c) amended & para. (d) added, 57 FR 56446, Nov. 30, 1992, effective Jan. 4, 1993]

37 CFR 1.60 PRACTICE

The 37 CFR 1.60 practice was developed to provide a procedure for filing a continuation or divisional application where hardships existed in obtaining the signature of the inventor on such an application during the pendency of the prior application. It is suggested that the use of the 37 CFR 1.60 practice be limited to such instances in view of the additional work required by the Office to enter preliminary amendments.

Chapter 200 Types, Cross−Noting, and Status of Application

201 Types of Applications
201.01 Sole
201.02 Joint
201.03 Correction of Inventorship in an Application
201.04 Parent Application
201.04(a) Original Application
201.04(b) Provisional Application
201.05 Reissue Application
201.06 Division Application
201.06(a) Division−Continuation Program
201.06(b) File Wrapper Continuing Procedure
201.07 Continuation Application
201.08 Continuation−in−Part Application
201.09 Substitute Application
201.10 Refile
201.11 Continuity Between Applications: When Entitled to Filing Date
201.11(a) Filing of Continuation or Continuation−in−Part Application During Pendency of International Application Designating the United States
201.12 Assignment Carries Title
201.13 Right of Priority of Foreign Application
201.13(a) Right of Priority Based Upon an Application for an Inventor's Certificate
201.13(b) Right of Priority Based Upon an International Application Filed Under the Patent Cooperation Treaty
201.14 Right of Priority, Formal Requirements
201.14(a) Right of Priority, Time for Filing Papers
201.14(b) Right of Priority, Papers Required
201.14(c) Right of Priority, Practice
201.14(d) Proper Identification of Priority Application
201.15 Right of Priority, Overcoming a Reference
201.16 Using Certificate of Correction to Perfect Claim for Priority Under 35 U.S.C. 119 >a−d<
202 Cross−Noting
202.01 In Specification
202.02 Notation on File Wrapper **>Regarding Prior U.S. Applications, Including Provisional Applications<
202.03 Notation on File Wrapper When Priority Is Claimed for Foreign Application
202.04 In Oath or Declaration
202.05 In Case of Reissues
203 Status of Applications
203.01 New
203.02 Rejected
203.03 Amended
203.04 Allowed or in Issue
203.05 Abandoned
203.06 Incomplete
203.07 Abandonment for Failure to Pay Issue Fee
203.08 Status Inquiries
203.08(a) Congressional and Other Official Inquiries

201 Types of Applications [R−2]

35 U.S.C. 111 Application.

(a) IN GENERAL.—

(1) WRITTEN APPLICATION.—An application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the Commissioner.

(2) CONTENTS.—Such application shall include—

(A) a specification as prescribed by section 112 of this title;

(B) a drawing as prescribed by section 113 of this title; and

(C) an oath by the applicant as prescribed by section 115 of this title.

(3) FEE AND OATH.—The application must be accompanied by the fee required by law. The fee and oath may be submitted after the specification and any required drawing are submitted, within such period and under such conditions, including the payment of a surcharge, as may be prescribed by the Commissioner.

(4) FAILURE TO SUBMIT.—Upon failure to submit the fee and oath within such prescribed period, the application shall be regarded as abandoned, unless it is shown to the satisfaction of the Commissioner that the delay in submitting the fee and oath was unavoidable or unintentional. The filing date of an application shall be the date on which the specification and any required drawing are received in the Patent and Trademark Office.

(b) PROVISIONAL APPLICATION.—

(1) AUTHORIZATION.—A provisional application for patent shall be made or authorized to be made by the inventor, except as otherwise provided in this title, in writing to the Commissioner. Such application shall include—

(A) a specification as prescribed by the first paragraph of section 112 of this title; and

(B) a drawing as prescribed by section 113 of this title.

(2) CLAIM.—A claim, as required by the second through fifth paragraphs of section 112, shall not be required in a provisional application.

(3) FEE.—(A) The application must be accompanied by the fee required by law.

(B) The fee may be submitted after the specification and any required drawing are submitted, within such period and under such conditions, including the payment of a surcharge, as may be prescribed by the Commissioner.

(C) Upon failure to submit the fee within such prescribed period, the application shall be regarded as abandoned, unless it is shown to the satisfaction of the Commissioner that the delay in submitting the fee was unavoidable or unintentional.

(4) FILING DATE.—The filing date of a provisional application shall be the date on which the specification and any required drawing are received in the Patent and Trademark Office.

(5) ABANDONMENT.—The provisional application shall be regarded as abandoned 12 months after the filing date of such application and shall not be subject to revival thereafter.

(6) OTHER BASIS FOR PROVISIONAL APPLICATION.—Subject to all the conditions in this subsection and section 119(e) of this title, and as prescribed by the Commissioner, an application for patent filed under subsection (a) may be treated as a provisional application for patent.

(7) NO RIGHT OF PRIORITY OR BENEFIT OF EARLIEST FILING DATE.—A provisional application shall not be entitled to the right of priority of any other application under section 119 or 365(a) of this title or to the benefit of an earlier filing date in the United States under section 120, 121, or 365(c) of this title.

201.05 Reissue Application

A reissue application is an application for a patent to take the place of an unexpired patent that is defective in some one or more particulars. A detailed treatment of reissues will be found in chapter 1400.

201.06 Division Application [R–1]

A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division." It may be filed pursuant to 37 CFR 1.53>(b)(1)<, 37 CFR 1.60 or 37 CFR 1.62. Both must have at least one common applicant. The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application. >An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "division" of the provisional application since the application will have its patent term calculated from its filing date, whereas an application filed under 35 U.S.C. 120, 121, or 365(c) will have its patent term calculated from the date on which the earliest application was filed, provided a specific reference is made to the earlier filed application(s). 35 U.S.C. 154(a)(2) and (a)(3).<

In the interest of expediting the processing of newly filed divisional applications, filed as a result of a restriction requirement, applicants are requested to include the appropriate Patent and Trademark Office classification of the divisional application and the status and location of the parent application, on the papers submitted. The appropriate classification for the divisional application may be found in the Office communication of the parent case wherein the requirement was made. It is suggested that this classification designation be placed in the upper right hand corner of the letter of transmittal accompanying these divisional applications.

Use Form Paragraph 2.01 to remind applicant of possible division status.

¶ *2.01 Definition of Division*

This application appears to be a division of ** >Application< No. [1] filed [2]. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division". The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application.

Examiner Note:

1. In bracket 1, insert the ** >application no. (series code and serial number)< of >the< parent application.

2. In bracket 2, insert the filing date of parent application.

>3. An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "division" of the provisional application since the application will have its patent term calculated from its filing date, whereas an application filed under 35 U.S.C. 120, 121, or 365(c) will have its term calculated from the date on which the earliest application was filed, provided a specific reference is made to the earlier filed application(s), 35 U.S.C. 154(a)(2) and (a)(3).<

A design application may be considered to be a division of a utility application >(but not of a provisional application)<, and is entitled to the filing date thereof if the drawings of the earlier filed utility application show the same article as that in the design application sufficiently to comply with 35 U.S.C. 112, first paragraph. However, such a divisional design application may only be filed under the procedure set forth in 37 CFR 1.53>(b)(1)< not under 37 CFR 1.60 or 37 CFR 1.62. See MPEP § 1504.20.

While a divisional application may depart from the phraseology used in the parent case there may be no departure therefrom in substance or variation in the disclosure that would amount to "new matter" if introduced by amendment into the parent case. Compare MPEP § 201.08 and § 201.11.

For notation to be put on the file wrapper by the examiner in the case of a divisional application, see MPEP § 202.02.

201.06(a) Division–Continuation Program [R–2]

37 CFR 1.60. Continuation or divisional application for invention disclosed in a prior >nonprovisional< application

(a) [Reserved]

(b) An applicant may omit signing of the oath or declaration in a continuation or divisional application (filed under the conditions specified in 35 U.S.C.120 or 121 and § 1.78(a)) if:

(1) the prior application was a nonprovisional application and a complete application as set forth in § 1.51(a)(1);

(2) applicant indicates that the application is being filed pursuant to this section and files a true copy of the prior complete application as filed including the specification (with claims), drawings, oath or declaration showing the signature or an indication it was signed, and any amendments referred to in the oath or declaration filed to complete the prior application;

(3) the inventors named in the continuation or divisional application are the same or less than all the inventors named in the prior application; and

Chapter 200 Types, Cross-Noting, and Status of Application

201 Types of Applications
201.01 Sole
201.02 Joint
201.03 Correction of Inventorship in an Application
201.04 Parent Application
201.04(a) Original Application
201.04(b) Provisional Application
201.05 Reissue Application
201.06 Divisional Application
201.06(a) Former 37 CFR 1.60 Divisional-Continuation Procedure
201.06(b) Former 37 CFR 1.62 File Wrapper Continuing Procedure
201.06(c) 37 CFR 1.53(b) and 37 CFR 1.63(d) Divisional-Continuation Procedure
201.06(d) 37 CFR 1.53(d) Continued Prosecution Application (CPA) Practice
201.07 Continuation Application
201.08 Continuation-in-Part Application
201.09 Substitute Application
201.10 Refile
201.11 Claiming the Benefit of an Earlier Filing Date Under 35 U.S.C. 120 and 119(e)
201.11(a) Filing of Continuation or Continuation-in-Part Application During Pendency of International Application Designating the United States
201.12 Title to an Application Claiming Benefit of an Earlier Application
201.13 Right of Priority of Foreign Application
201.13(a) Right of Priority Based Upon an Application for an Inventor's Certificate
201.13(b) Right of Priority Based Upon an International Application Filed Under the Patent Cooperation Treaty
201.14 Right of Priority, Formal Requirements
201.14(a) Right of Priority, Time for Filing Papers
201.14(b) Right of Priority, Papers Required
201.14(c) Right of Priority, Practice
201.14(d) Proper Identification of Priority Application
201.15 Right of Priority, Overcoming a Reference
201.16 Using Certificate of Correction to Perfect Claim for Priority Under 35 U.S.C. 119(a)-(d) or (f)
201.17 Incorporation by Reference Under 37 CFR 1.57(a)
202 Cross-Noting
202.02 Notation in File History Regarding Prior U.S. Applications, Including Provisional Applications
202.03 Notation in File History When Priority Is Claimed for Foreign Application
202.04 In Oath or Declaration
203 Status of Applications
203.01 New
203.02 Rejected
203.03 Amended
203.04 Allowed or in Issue
203.05 Abandoned
203.06 Incomplete
203.08 Status Inquiries
203.08(a) Congressional and Other Official Inquiries

201 Types of Applications [R-3]

35 U.S.C. 111. Application.

(a) IN GENERAL.—

(1) WRITTEN APPLICATION.—An application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the Director.

(2) CONTENTS.—Such application shall include—

(A) a specification as prescribed by section 112 of this title;

(B) a drawing as prescribed by section 113 of this title; and

(C) an oath by the applicant as prescribed by section 115 of this title.

(3) FEE AND OATH.—The application must be accompanied by the fee required by law. The fee and oath may be submitted after the specification and any required drawing are submitted, within such period and under such conditions, including the payment of a surcharge, as may be prescribed by the Director.

(4) FAILURE TO SUBMIT.—Upon failure to submit the fee and oath within such prescribed period, the application shall be regarded as abandoned, unless it is shown to the satisfaction of the Director that the delay in submitting the fee and oath was unavoidable or unintentional. The filing date of an application shall be the date on which the specification and any required drawing are received in the Patent and Trademark Office.

(b) PROVISIONAL APPLICATION.—

(1) AUTHORIZATION.—A provisional application for patent shall be made or authorized to be made by the inventor, except as otherwise provided in this title, in writing to the Director. Such application shall include—

(A) a specification as prescribed by the first paragraph of section 112 of this title; and

(B) a drawing as prescribed by section 113 of this title.

(2) CLAIM.—A claim, as required by the second through fifth paragraphs of section 112, shall not be required in a provisional application.

(3) FEE.—

(A) The application must be accompanied by the fee required by law.

(B) The fee may be submitted after the specification and any required drawing are submitted, within such period and

201.05 Reissue Application [R-3]

A reissue application is an application for a patent to take the place of an unexpired patent that is defective **>as a result of an error in the patent which was made without deceptive intention.< A detailed treatment of **>reissue applications can< be found in Chapter 1400.

201.06 Divisional Application [R-2]

A later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division." >A divisional application is often filed as a result of a restriction requirement made by the examiner.< The divisional application must claim the benefit of the prior nonprovisional application under 35 U.S.C. 121 or 365(c). *>See MPEP § 201.11 for the conditions for receiving the benefit of the filing date of the prior application. The divisional application should set forth at least the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

Divisional applications of utility or plant applications must be filed under 37 CFR 1.53(b). Divisional applications of design applications< may be filed pursuant to 37 CFR 1.53(b) or 1.53(d). 37 CFR 1.60 and 1.62 have been deleted as of December 1, 1997.

**>Effective July 14, 2003, continued prosecution application (CPA) practice set forth in 37 CFR 1.53(d) has been eliminated as to utility and plant applications.< An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "division" of the provisional application since the application will have its patent term calculated from its filing date, whereas an application filed under 35 U.S.C. 120, 121, or 365(c) will have its patent term calculated from the date on which the earliest application was filed, provided a specific reference is made to the earlier filed application(s). 35 U.S.C. 154(a)(2) and (a)(3).

In the interest of expediting the processing of newly filed divisional applications filed as a result of a restriction requirement, applicants are requested to include the appropriate U.S. Patent and Trademark Office classification of the divisional application and the status and *>assigned art unit< of the parent application on the papers submitted. The appropriate classification for the divisional application may be found in the Office communication of the parent application wherein the >restriction< requirement was made. It is suggested that this classification designation be placed in the upper right hand corner of the letter of transmittal accompanying these divisional applications or in an application data sheet as set forth in 37 CFR 1.76(b)(3).

Use form paragraph 2.01 to remind applicant of possible divisional status.
**>

¶ *2.01 Definition of Division*

This application appears to be a division of Application No. **[1],** filed **[2]**. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division." The divisional application should set forth the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

Examiner Note:

1. In bracket 1, insert the Application No.(series code and serial no.) of the parent application.
2. In bracket 2, insert the filing date of the parent application.
3. An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "division" of the provisional application since the application will have its patent term calculated from its filing date, whereas an application filed under 35 U.S.C. 120, 121, or 365(c) will have its term calculated from the date on which the earliest application was filed, provided a specific reference is made to the earlier filed application(s), 35 U.S.C. 154(a)(2) and (a)(3).

<

A design application may be considered to be a division of a utility application (but not of a provisional application), and is entitled to the filing date thereof if the drawings of the earlier filed utility application show the same article as that in the design application sufficiently to comply with 35 U.S.C. 112, first paragraph. However, such a divisional design application may only be filed under the procedure set forth in 37 CFR 1.53(b) not under 37 CFR 1.53(d). ** See MPEP § 1504.20.

While a divisional application may depart from the phraseology used in the parent application there may be no departure therefrom in substance or variation in the disclosure that would amount to "new matter" if introduced by amendment into the parent application. Compare MPEP § 201.08 and § 201.11.

For notation to be put *>in< the file *>history< by the examiner in the case of a divisional application, see MPEP § 202.02.

201.06(a) Former 37 CFR 1.60 Divisional-Continuation Procedure [R-2]

*** 37 CFR 1.60 was deleted effective December 1, 1997. See 1203 O.G. 63, October 21, 1997. A continuation or divisional application filed under 37 CFR 1.60 on or after December 1, 1997, will automatically be treated as an application filed under 37 CFR 1.53(b). All continuation and divisional applications filed under 37 CFR 1.60 prior to December 1, 1997 will continue to be processed and examined under the procedures set forth in former 37 CFR 1.60. **>For more information pertaining to practice and procedure under former 37 CFR 1.60, see MPEP § 201.06(a) in the MPEP 8th Edition, Rev. 1 (February 2003)(available on the USPTO web site at www.uspto.gov/web/offices/pac/mpep/mpep.htm).<**

201.06(b) Former 37 CFR 1.62 File Wrapper Continuing Procedure [R-2]

***37 CFR 1.62 was deleted effective December 1, 1997. See 1203 O.G. 63, October 21, 1997. A >request for a< continuation or divisional application filed under former 37 CFR 1.62 on or after December 1, 1997, >, in an application that was filed on or after June 8, 1995,< will be treated as ** a request for continued examination (RCE) under 37 CFR *>1.114<, see MPEP 706.07(h), paragraph IV. **>A request< filed on or after December 1, 1997, under former 37 CFR 1.62 *>for< a continuation-in-part (CIP) application, **>, or for a continuation or divisional of an application having a filing date before June 8, 1995,< will be treated as an improper application.**

**

All continuation, divisional and CIP applications filed under former 37 CFR 1.62 prior to December 1, 1997, will continue to be processed and examined under the procedures set forth in former 37 CFR 1.62. **>For more information pertaining to practice and procedure under former 37 CFR 1.62, see MPEP § 201.06(b) in the MPEP 8th Edition, Rev. 1 (February 2003)(available on the USPTO web site at www.uspto.gov/web/offices/pac/mpep/mpep.htm).<

201.06(c) 37 CFR 1.53(b) and 37 CFR 1.63(d) Divisional-Continuation Procedure [R-5]

37 CFR 1.53. Application number, filing date, and completion of application.

*****

(b) *Application filing requirements - Nonprovisional application*. The filing date of an application for patent filed under this section, except for a provisional application under paragraph (c) of this section or a continued prosecution application under paragraph (d) of this section, is the date on which a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75, and any drawing required by § 1.81(a) are filed in the Patent and Trademark Office. No new matter may be introduced into an application after its filing date. A continuing application, which may be a continuation, divisional, or continuation-in-part application, may be filed under the conditions specified in 35 U.S.C. 120, 121 or 365(c) and § 1.78(a).

(1) A continuation or divisional application that names as inventors the same or fewer than all of the inventors named in the prior application may be filed under this paragraph or paragraph (d) of this section.

(2) A continuation-in-part application (which may disclose and claim subject matter not disclosed in the prior application) or a continuation or divisional application naming an inventor not named in the prior application must be filed under this paragraph.

*****

37 CFR 1.63. Oath or Declaration.

*****

(d)(1)A newly executed oath or declaration is not required under § 1.51(b)(2) and § 1.53(f) in a continuation or divisional application, provided that:

(i) The prior nonprovisional application contained an oath or declaration as prescribed by paragraphs (a) through (c) of this section;

(ii) The continuation or divisional application was filed by all or by fewer than all of the inventors named in the prior application;

(iii) The specification and drawings filed in the continuation or divisional application contain no matter that would have been new matter in the prior application; and

(iv) A copy of the executed oath or declaration filed in the prior application, showing the signature or an indication thereon

Chapter 800 Restriction >in applications filed under 35 U.S.C. 111<; Double Patenting

801 Introduction
802 Basis for Practice in Statute and Rules
802.01 Meaning of "Independent", "Distinct"
802.02 Definition of Restriction
803 Restriction — When Proper
803.01 Review by Primary Examiner
803.02 Restriction - Markush Claims
804 Definition of Double Patenting
804.01 Nullification of Double Patenting Rejection
804.02 Terminal Disclaimer Avoiding Double Patenting Rejection
804.03 Treatment of Conflicting Claims in Commonly Owned Cases of Different Inventive Entities
804.04 Submission to Group Director
805 Effect of Improper Joinder in Patent
806 Determination of Distinctness or Independence of Claimed Inventions
806.01 Compare Claimed Subject Matter
806.02 Patentability Over the Prior Art Not Considered
806.03 Single Embodiment, Claims Defining Same Essential Features
806.04 Independent Inventions
806.04(a) Species — Genus
806.04(b) Species May Be Related Inventions
806.04(c) Subcombination Not Generic to Combination
806.04(d) Definition of a Generic Claim
806.04(e) Claims Restricted to Species
806.04(f) Claims Restricted to Species, by Mutually Exclusive Characteristics
806.04(h) Species Must Be Patentably Distinct From Each Other and From Genus
806.04(i) Generic Claims Presented for First Time After Issue of Species
806.04(j) Generic Claims in One Patent Only
806.05 Related Inventions
806.05(a) Combination and Subcombination or Element
806.05(b) Old Combination — Novel Subcombination
806.05(c) Criteria of Distinctness for Combination, Subcombination or Element of a Combination
806.05(d) Subcombinations Usable Together
806.05(e) Process and Apparatus for Its Practice — Distinctness
806.05(f) Process of Making and Product Made — Distinctness
806.05(g) Apparatus and Product Made — Distinctness
806.05(h) Product and Process of Using
806.05(i) Product, Process of Making, and Process of Using — Product Claim Not Allowable
807 Patentability Report Practice Has No Effect on Restriction Practice
808 Reasons for Insisting Upon Restriction
808.01 Independent Inventions
808.01(a) Species
808.02 Related Inventions
809 Claims Linking Distinct Inventions
809.02 Generic Claim Linking Species
809.02(a) Election Required
809.02(b) Election Required — Generic Claim Allowable
809.02(c) Action Following Election
809.02(d) No Species Claims
809.02(e) Generic Claim Allowable in Substance
809.03 Linking Claims
809.04 Retention of Claims to Non-Elected Invention
810 Action on the Merits
810.01 Not Objectionable When Coupled With Requirement
810.02 Usually Deferred
810.03 Given on Elected Invention When Requirement Is Made Final
811 Time for Making Requirement
811.02 Even After Compliance With Preceding Requirement
811.03 Repeating After Withdrawal — Proper
811.04 Proper Even Though Grouped Together in Parent Case
812 Who Should Make the Requirement
812.01 Telephone Restriction Practice
814 Indicate Exactly How Application Is To Be Restricted
815 Make Requirement Complete
816 Give Reasons for Holding of Independence or Distinctness
817 Outline of Letter for Restriction Requirement between Distinct Inventions
818 Election and Response
818.01 Election Fixed by Action on Claims
818.02 Election Other Than Express
818.02(a) By Originally Presented Claims
818.02(b) Generic Claims Only — No Election of Species
818.02(c) By Optional Cancellation of Claims
818.03 Express Election and Traverse
818.03(a) Response Must Be Complete
818.03(b) Must Elect, Even When Requirement Is Traversed
818.03(c) Must Traverse To Preserve Right of Petition
818.03(d) Traverse of Non-Allowance of Linking Claims
818.03(e) Applicant Must Make Own Election
819 Office Generally Does Not Permit Shift
819.01 Office May Waive Election and Permit Shift
820 Not an Election; Permissible Shift
820.01 Old Combination Claimed — Not an Election
820.02 Interference Issues — Not an Election
821 Treatment of Claims Held to be Drawn to Non-Elected Inventions
821.01 After Election With Traverse
821.02 After Election Without Traverse
821.03 Claims for Different Invention Added After an Office Action
822 Claims to Inventions That Are Not Distinct in Plural Applications of Same Inventive Entity
822.01 Co-pending Before the Examiner
823 Unity of Invention Under the Patent Cooperation Treaty

801 Introduction [R-8]

>This Chapter is limited to a discussion of the<* subject of restriction ** and double patenting ** under U.S.C. Title 35 ** and the Rules of Practice >as it relates to national applications filed under 35 U.S.C. 111. The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority and in applications entering the national stage under 35 U.S.C. 371 as a Designated or

Claim [1] provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim [2] of copending application serial no. [3] in view of [4].

This is a provisional obviousness-type double patenting rejection.

Examiner Note:

1. This paragraph is used for obviousness-type double patenting rejections where the primary reference is a conflicting application.

2. If the conflicting claims are in a patent, do not use this form paragraph. Use form paragraph 7.25.

3. This paragraph may be used where the conflicting claims are in a copending application that is:

(a) by the same inventive entity, or

(b) by a different inventive entity and is commonly assigned, or

(c) not commonly assigned but has at least one inventor in common.

4. Form Paragraph 7.26 must follow one of paragraphs 7.24 - 7.25.1 and must be used only once in an Office action.

5. If the conflicting cases are currently commonly assigned but the file does not establish that the conflicting inventions were commonly owned at the time the later invention was made, form paragraph 8.28 may be used in place of or in addition to this form paragraph to also resolve any issues of priority of invention under 102(f) and/or (g).

6. In bracket 3, insert the number of the conflicting application.

7. An explanation of the obviousness-type double patenting rejection must follow this paragraph.

8. A provisional obviousness-type double patenting rejection should also be made in the other conflicting application.

9. If evidence is also of record to show that either application is prior art unto the other under 35 U.S.C. 102(f) or 102(g), and the copending application has not been disqualified as prior art in a 103 rejection based on common ownership, a rejection should additionally be made under 102(f)/103 or 102(g)/ 103 using form paragraph 7.21.

10. If the disclosure of one application may be used to support a rejection of the other and the applications have different inventive entities and different U.S. filing dates, use form paragraph 7.21.1 to additionally make a 102(e)/103 rejection.

¶ 7.26 Obviousness-type Double Patenting, Basis

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Examiner Note:

This paragraph must be used only once in an Office action and must follow one of form Paragraphs 7.24 - 7.25.1.

The Court of Customs and Patent Appeals has held that a terminal disclaimer is ineffective **>for the "same invention" type double patenting situation<, where it is attempted to twice claim the same invention. However, the "obviousness" type double patenting rejection may be obviated by a terminal disclaimer.**>Such a disclaimer is required in each application since the Office cannot ensure which application will issue first.<

The inventive entity is the sole inventor or the joint inventors listed on a patent or patent application. A sole inventor in one application and joint inventors in another application cannot constitute a single or the same inventive entity, even if the sole inventor is one of the joint inventors. Likewise, two sets of joint inventors do not constitute a single inventive entity if any individual inventor is included in one set who is not also included in the other set.

804.01 Nullification of Double Patenting Rejection [R-8]

35 U.S.C. 121, third sentence, provides that where the Office requires restriction **, the patent of either the parent or any divisional application thereof conforming to the requirement cannot be used as a reference against the other. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restriction where the claims define essentially the same inventions in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.**

A. SITUATIONS WHERE THE DOUBLE PATENTING PROTECTION UNDER 35 U.S.C. 121 DOES NOT APPLY

(a) The applicant voluntarily files two or more cases without requirement by the examiner.

(b) The claims of the different applications or patents are not consonant with the requirement made by the examiner, due to the fact that the claims have been changed in material respects from the claims at the time the requirement was made.

(c) The requirement was written in a manner which made it clear to applicant that the requirement was made subject to the non allowance of generic or other linking claims and such linking claims are subsequently allowed. Therefore, if a generic or linking claim is subsequently allowed, the restriction requirement should be removed.

(d) The requirement for restriction (holding of lack of unity of invention) was only made in an international application >by the International Searching Authority or the International Preliminary Examining Authority<.

B. SITUATIONS WHERE THE DOUBLE PATENTING PROTECTION UNDER 35 U.S.C. 121 APPARENTLY APPLIES

It is considered that the prohibition against holdings of double patenting applies to requirements for restriction between the related subjects treated in >MPEP< §§ 806.04 through 806.05(i), namely, between combination and subcombination thereof, between subcombinations disclosed as usable together, between process and apparatus for its practice, between process and product made by such process and between apparatus and product made by such apparatus, etc., *so long as the claims in each case >are< filed as a result of such requirement* **.

Chapter 1400 Correction of Patents

1400.01 Introduction
1401 Reissue
1402 Grounds for Filing
1403 Diligence in Filing
1404 Submission of Papers Where Reissue Patent Is in Litigation
1405 Reissue and Patent Term
1406 Citation and Consideration of References Cited in Original Patent
1410 Content of Reissue Application
1410.01 Reissue Applicant, Oath or Declaration, and Consent of all Assignees
1411 Form of Specification
1411.01 Certificate of Correction or Disclaimer in Original Patent
1411.02 New Matter
1412 Content of Claims
1412.01 Reissue Claims Must Be for Same General Invention
1412.02 Recapture of Canceled Subject Matter
1412.03 Broadening Reissue Claims
1412.04 Correction of Inventorship
1413 Drawings
1414 Content of Reissue Oath/Declaration
1414.01 Supplemental Reissue Oath/ Declaration
1415 Reissue Application and Issue Fees
1415.01 Maintenance Fees on the Original Patent
1416 No Physical Surrender of Original Patent
1417 Claim for Benefit Under 35 U.S.C. 119(a)-(d)
1418 Notification of Prior/Concurrent Proceedings and Decisions Thereon, and of Information Known To Be Material to Patentability
1430 Reissue Files Open to the Public and, Notice of Filing Reissue Announced in, Official Gazette
1440 Examination of Reissue Application
1441 Two-Month Delay Period
1441.01 Protest in Reissue Applications
1442 Special Status
1442.01 Litigation-Related Reissues
1442.02 Concurrent Litigation
1442.03 Litigation Stayed
1442.04 Litigation Involving Patent
1442.05 Court Ordered Filing of Reissue Application
1443 Initial Examiner Review
1444 Review of Reissue Oath/Declaration
1445 Reissue Application Examined in Same Manner as Original Application
1448 Fraud, Inequitable Conduct, or Duty of Disclosure Issues
1449 Protest Filed in Reissue Where Patent Is in Interference
1449.01 Concurrent Office Proceedings
1449.02 Interference in Reissue
1450 Restriction and Election of Species Made in Reissue Application
1451 Divisional Reissue Applications; Continuation Reissue Applications Where the Parent is Pending
1452 Request for Continued Examination of Reissue Application
1453 Amendments to Reissue Applications
1454 Appeal Brief
1455 Allowance and Issue
1456 Reissue Review
1457 Design Reissue Applications and Patents
1460 Effect of Reissue
1470 Public Access of Reissue Applications
1480 Certificates of Correction — Office Mistake
1480.01 Expedited Issuance of Certificates of Correction - Error Attributable to Office
1481 Certificates of Correction - Applicant's Mistake
1481.01 Correction of Assignees' Names
1481.02 Correction of Inventors' Names
1481.03 Correction of 35 U.S.C. 119 and 35 U.S.C. 120 Benefits
1485 Handling of Request for Certificates of Correction
1490 Disclaimers

1400.01 Introduction [R-2]

A patent may be corrected or amended in four ways, namely:

(A) by reissue,

(B) by the issuance of a certificate of correction which becomes a part of the patent,

(C) by disclaimer, and

(D) by reexamination.

The first three ways are discussed in this chapter while the fourth way (reexamination) is discussed in MPEP Chapter 2200> for *ex parte* reexamination and MPEP Chapter 2600 for *inter partes* reexamination<.

1401 Reissue [R-3]

35 U.S.C. 251 Reissue of defective patents.

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a

new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

The Director may issue several reissued patents for distinct and separate parts of the thing patented, upon demand of the applicant, and upon payment of the required fee for a reissue for each of such reissued patents.

The provisions of this title relating to applications for patent shall be applicable to applications for reissue of a patent, except that application for reissue may be made and sworn to by the assignee of the entire interest if the application does not seek to enlarge the scope of the claims of the original patent.

No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

The provisions of **35 U.S.C. 251** permit the reissue of a patent to correct an error in the patent made without any deceptive intention and provide criteria for the reissue. **37 CFR 1.171** through *>**1.178**< are rules directed to reissue.

1402 Grounds for Filing [R-9]

A reissue application is filed to correct an error in the patent which was made without any deceptive intention, where, as a result of the error, the patent is deemed wholly or partly inoperative or invalid. An error in the patent arises out of an error in conduct which was made in the preparation and/or prosecution of the application which became the patent.

There must be at least one error in the patent to provide grounds for reissue of the patent. If there is no error in the patent, the patent will not be reissued. The present section provides a discussion of what may be considered an error in the patent upon which to base a reissue application.

In accordance with **35 U.S.C. 251**, the error upon which a reissue is based must be one which causes the patent to be "deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent." Thus, an error under **35 U.S.C. 251** *has not been presented* where the correction to the patent is one of spelling, or grammar, or a typographical, editorial or clerical error which does not cause the patent to be deemed wholly or partly inoperative or invalid for the reasons specified in **35 U.S.C. 251**.

These corrections to a patent do not provide a basis for reissue (although these corrections may also be included in a reissue application, where a **35 U.S.C. 251** error is already present).

These corrections may be made via a certificate of correction; see **MPEP § 1481**.

The most common bases for filing a reissue application are:

(A) the claims are too narrow or too broad;
(B) the disclosure contains inaccuracies;
(C) applicant failed to or incorrectly claimed foreign priority; and
(D) applicant failed to make reference to or incorrectly made reference to prior copending applications.

> An error under **35 U.S.C. 251 may be based upon the addition of a claim or claims that is/are narrower in scope than the existing patent claims, without any narrowing of the existing patent claims. See *In re Tanaka*, 640 F.3d 1246, 1251, 98 USPQ2d 1331, 1334 (Fed. Cir. 2011).<

A reissue applicant's failure to timely file a divisional application covering the non-elected invention(s) following a restriction requirement is not considered to be error causing a patent granted on elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Thus, such applicant's error is not correctable by reissue of the original patent under **35 U.S.C. 251**. See **MPEP § 1412.01**.

An attorney's failure to appreciate the full scope of the invention was held to be an error correctable through reissue in the decision of *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984). >In *Medrad, Inc. v. Tyco Healthcare Group LP*, 466 F.3d 1047, 80 USPQ2d 1526 (Fed. Cir. 2006), the court rejected an argument that a **35 U.S.C. 251** error was limited to defects in the specification, drawings, and claims. Instead, the court explained that the correctable error could be "any error that causes a patentee to claim more or less than he had a right to claim." 466 F.3d at 1052, 80 USPQ2d at 1529. In *Medrad*, the specific error was the failure to submit a supplemental reissue declaration during prosecution of a prior reissue patent.< The correction of misjoinder of inventors in divisional reissues has been held to be a ground for reissue. See *Ex parte Scudder*, 169 USPQ 814 (Bd. App. 1971). The Board of Appeals held in *Ex parte Scudder*, 169 USPQ at 815, that **35 U.S.C. 251** authorizes reissue applications to correct misjoinder of inventors where **35 U.S.C. 256** is inadequate.

Reissue may no longer be necessary under the facts in *Ex parte Scudder, supra,* in view of **35 U.S.C. 116** which provides, *inter alia*, that:

> "Inventors may apply for a patent jointly even though . . . (3) each did not make a contribution to the subject matter of every claim in the patent."

See also **37 CFR 1.45(b)(3)**.

If the only change being made in the patent is correction of the inventorship, this can be accomplished by filing a request for a certificate of correction under the provisions of **35 U.S.C. 256** and **37 CFR 1.324**. See **MPEP § 1412.04** and **§ 1481**. A Certificate of Correction will be issued if all parties are in agreement and the inventorship issue is not contested. However, if applicant chooses to file a reissue application to correct the inventorship (as opposed to choosing the Certificate of Correction route), applicant may do so because misjoinder of inventors is an error that is correctable by reissue under **35 U.S.C. 251**.

A reissue was granted in *Brenner v. State of Israel*, 400 F.2d 789, 158 USPQ 584 (D.C. Cir. 1968), where the only ground urged was failure to file a certified copy of the original foreign application to obtain the right of foreign priority under **35 U.S.C. 119(a)-(d)** before the patent was granted.

In *Brenner* , the claim for priority had been made in the prosecution of the original patent, and it was only necessary to submit a certified copy of the priority document in the reissue application to perfect priority. Reissue is also available to convert the "error" in failing to take any steps to obtain the right of foreign priority under **35 U.S.C. 119(a)-(d)** before the patent was granted. See *Fontijn v. Okamoto* , 518 F.2d 610, 622, 186 USPQ 97, 106 (CCPA 1975) ("a patent may be reissued for the purpose of establishing a claim to priority which was not asserted, or which was not perfected during the prosecution of the original application"). In a situation where it is necessary to submit for the first time both the claim for priority and the certified copy of the priority document in the reissue application, and the patent to be reissued resulted from a utility or plant application which became the patent to be reissued was filed on or after November 29, 2000, the reissue applicant must (where it is necessary to submit for the first time the claim for priority) also file a petition for an unintentionally delayed priority claim under **37 CFR 1.55(c)** in addition to filing a reissue application. See **MPEP § 201.14(a)**.

The courts have not addressed the question of correction of the failure to adequately claim benefit under **35 U.S.C. 119(e)** in the application (which became the patent to be reissued) via reissue. If the application which became the patent to be reissued was filed before November 29, 2000, correction as to benefit under **35 U.S.C. 119(e)** would be permitted in a manner somewhat analogous to that of the priority correction discussed above. Where the application, which became the patent to be reissued, was filed on or after November 29, 2000, reissue may be employed to correct an applicant's mistake by adding or correcting a benefit claim under **35 U.S.C. 119(e)**. A petition under **37 CFR 1.78(a)(6)** for an unintentionally delayed claim under **35 U.S.C. 119(e)** would not be required in addition to filing a reissue application.

Section 4503 of the American Inventors Protection Act of 1999 (AIPA) amended **35 U.S.C. 119(e)(1)** to state that:

> No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section ***during the pendency of the application***. (Emphasis added.)

The court in *Fontijn* held that **35 U.S.C. 251** was sufficiently broad to correct a patent where the applicant failed to assert or failed to perfect a claim for foreign priority during the prosecution of the original application even though **35 U.S.C. 119(b)** at that time required a claim and a certified copy of the foreign application to be filed *before the patent is granted*. Similarly, the Office may grant a reissue for adding or correcting a benefit claim under **35 U.S.C. 119(e)** that requires the benefit claim to a provisional application be submitted *during the pendency of the application*.

Correction of failure to adequately claim benefit under **35 U.S.C. 120** in an earlier filed copending U.S. patent application was held a proper ground for reissue. *Sampson v. Comm'r Pat.* , 195 USPQ 136, 137 (D.D.C. 1976). If the utility or plant application which became the patent to be reissued was filed on or after November 29, 2000, the reissue applicant must file a petition for an

unintentionally delayed priority claim under 37 CFR 1.78(a)(3) in addition to filing a reissue application. See MPEP § 201.11. For treatment of an error involving disclaimer of a benefit claim under 35 U.S.C. 120, see MPEP § 1405. If the utility or plant application which became the patent to be reissued was filed before November 29, 2000 and therefore, not subject to the eighteen-month publication (e.g., one of the categories set forth in 37 CFR 1.78(a)(2)(ii)(A) – (C)), a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) would not be required to add/correct the benefit claim in the reissue application. This is so, even if the reissue application was filed on or after November 29, 2000. On the other hand, if applicant fails to file an amendment to add a claim for benefit of a prior-filed reissue application in a later-filed reissue application within the time period set forth in 37 CFR 1.78(a)(2), then a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) along with the surcharge set forth in 37 CFR 1.17(t) would be required if the later-filed reissue application is a utility or plant application filed on or after November 29, 2000 irrespective of whether the original application which became the original patent was filed before November 29, 2000. This is because the benefit claim is between the later-filed reissue application and the prior-filed reissue application and the benefit claim is not being added to make a correction as to a benefit of the original patent.

A reissue may be based on a drawing correction that is substantive in nature, because such a correction qualifies as correcting an "error" under 35 U.S.C. 251 that may properly be deemed to render the patent wholly or partly inoperative. A reissue application cannot be based on a non-substantive drawing change, such as a reference numeral correction or addition, the addition of shading, or even the addition of an additional figure merely to "clarify" the disclosure. Non-substantive drawing changes may, however, be included in a reissue application that corrects at least one substantive "error " under 35 U.S.C. 251.

1403 Diligence in Filing [R-3]

When a reissue application is filed within 2 years from the date of the original patent, a rejection on the grounds of lack of diligence or delay in filing the reissue should not normally be made. *Ex parte Lafferty*, 190 USPQ 202 (Bd. App. 1975); but see *Rohm & Haas Co. v. Roberts Chemical Inc.*, 142 F. Supp. 499, 110 USPQ 93 (S.W. Va. 1956), *rev'd on other grounds*, 245 F.2d 693, 113 USPQ 423 (4th Cir. 1957).

The fourth paragraph of 35 U.S.C. 251 states:

> "No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent."

Where any broadening reissue application is filed within two years from the date of the original patent, 35 U.S.C. 251 presumes diligence, and the examiner should not inquire why applicant failed to file the reissue application earlier within the two year period.

See MPEP § 1412.03 for broadening reissue practice. See also *In re Graff,* 111 F.3rd 874, 42 USPQ2d 1471 (Fed. Cir. 1997); *In re Bennett,* 766 F.2d 524, 528, 226 USPQ 413, 416 (Fed. Cir. 1985); *In re Fotland,* 779 F.2d 31, 228 USPQ 193 (Fed. Cir. 1985).

A reissue application that is filed on the 2-year anniversary date of the patent grant is considered as being filed within 2 years. See *Switzer v. Sockman,* 333 F.2d 935, 142 USPQ 226 (CCPA 1964) (a similar rule in interferences).

A reissue application can be granted a filing date without an oath or declaration, or without the >basic< filing fee>, search fee, or examination fee< being present. See 37 CFR 1.53(f). Applicant will be given a period of time to provide the missing parts and to pay the surcharge under *>37 CFR 1.16(f)<. See MPEP § 1410.01.

1404 Submission of Papers Where Reissue Patent Is in Litigation [R-7]

Marking of envelope: Applicants and protestors (see MPEP § 1901.03) submitting papers for entry in reissue applications of patents involved in litigation are requested to mark the outside envelope and the top right-hand portion of the papers with the words "REISSUE LITIGATION" and with the art unit or other area of the United States Patent and Trademark Office in which the reissue application is located, e.g., Commissioner for Patents, Board of Patent Appeals and Interferences, Office of Patent Legal Administration, Technology Center, Office of Patent Publication, etc. Marking of papers: Any "Reissue Litigation" papers mailed to the Office should be so marked. The markings preferably should be written in a bright color with a felt point marker. Papers marked "REISSUE LITIGATION" will be given special attention and expedited handling. ** See MPEP § 1442.01 through § 1442.04 for examination of litigation-related reissue applications. Protestor's participation, including the submission of papers, is limited in accordance with 37 CFR 1.291(c).

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Chapter 1400 Correction of Patents

1400.01 Introduction
1401 Reissue
1402 Grounds for Filing
1403 Diligence in Filing
1404 Submission of Papers Where Reissue Patent Is in Litigation
1405 Reissue and Patent Term
1406 Citation and Consideration of References Cited in Original Patent
1410 Content of Reissue Application
1410.01 Reissue Applicant, Oath or Declaration, and Consent of all Assignees
1411 Form of Specification
1411.01 Certificate of Correction or Disclaimer in Original Patent
1411.02 New Matter
1412 Content of Claims
1412.01 Reissue Claims Must Be for Same General Invention
1412.02 Recapture of Canceled Subject Matter
1412.03 Broadening Reissue Claims
1412.04 Correction of Inventorship
1413 Drawings
1414 Content of Reissue Oath/Declaration
1414.01 Supplemental Reissue Oath/ Declaration
1415 Reissue Application and Issue Fees
1415.01 Maintenance Fees on the Original Patent
1416 No Physical Surrender of Original Patent
1417 Claim for Benefit Under 35 U.S.C. 119(a)-(d)
1418 Notification of Prior/Concurrent Proceedings and Decisions Thereon, and of Information Known To Be Material to Patentability
1430 Reissue Files Open to the Public and, Notice of Filing Reissue Announced in, Official Gazette
1440 Examination of Reissue Application
1441 Two-Month Delay Period
1441.01 Protest in Reissue Applications
1442 Special Status
1442.01 Litigation-Related Reissues
1442.02 Concurrent Litigation
1442.03 Litigation Stayed
1442.04 Litigation Involving Patent
1442.05 Court Ordered Filing of Reissue Application
1443 Initial Examiner Review
1444 Review of Reissue Oath/Declaration
1445 Reissue Application Examined in Same Manner as Original Application
1448 Fraud, Inequitable Conduct, or Duty of Disclosure Issues
1449 Protest Filed in Reissue Where Patent Is in Interference
1449.01 Concurrent Office Proceedings
1449.02 Interference in Reissue
1450 Restriction and Election of Species Made in Reissue Application
1451 Divisional Reissue Applications; Continuation Reissue Applications Where the Parent is Pending
1452 Request for Continued Examination of Reissue Application
1453 Amendments to Reissue Applications
1454 Appeal Brief
1455 Allowance and Issue
1456 Reissue Review
1457 Design Reissue Applications and Patents
1460 Effect of Reissue
1470 Public Access of Reissue Applications
1480 Certificates of Correction — Office Mistake
1480.01 Expedited Issuance of Certificates of Correction - Error Attributable to Office
1481 Certificates of Correction - Applicant's Mistake
1481.01 Correction of Assignees' Names
1481.02 Correction of Inventors' Names
1481.03 Correction of 35 U.S.C. 119 and 35 U.S.C. 120 Benefits
1485 Handling of Request for Certificates of Correction
1490 Disclaimers

1400.01 Introduction [R-2]

A patent may be corrected or amended in four ways, namely:

(A) by reissue,

(B) by the issuance of a certificate of correction which becomes a part of the patent,

(C) by disclaimer, and

(D) by reexamination.

The first three ways are discussed in this chapter while the fourth way (reexamination) is discussed in MPEP Chapter 2200> for *ex parte* reexamination and MPEP Chapter 2600 for *inter partes* reexamination<.

1401 Reissue [R-3]

35 U.S.C. 251 Reissue of defective patents.

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a

the patent have been properly incorporated into the reissue application.

Certificate of Correction changes and disclaimer of claim(s) under 37 CFR 1.321(a) should be made without using underlining or brackets. *>Because< these are >retroactively a< part of the original patent and *>are< made before the reissue **>application will issue as a patent, they must< show up in the printed reissue patent document as part of the original patent, i.e., not in italics or bracketed. >If the changes are submitted improperly with underlining and brackets, the examiner will require correction by the applicant in the form of a replacement paragraph (or paragraphs) without such markings.< If the changes are extensive**, a clean copy of the specification with the Certificate of Correction changes in it may be *>required< by the examiner >after consulting with his/her supervisor<. **>For< the clean copy >of the specification< to be entered as a substitute specification, the reissue applicant must file a grantable petition under 37 CFR 1.183 for waiver of 37 CFR 1.125(d) and 37 CFR 1.173(a)(1). The examiner's *>requirement< for the clean copy will generally serve as sufficient basis for granting the petition.

1411.02 New Matter

New matter, that is, matter not present in the patent sought to be reissued, is excluded from a reissue application in accordance with 35 U.S.C. 251.

The claims in the reissue application must be for subject matter which the applicant had the right to claim in the original patent. *Any* change in the patent made via the reissue application should be checked to ensure that it does not introduce new matter. Note that new matter may exist by virtue of the omission of a feature or of a step in a method. See *United States Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.,* 315 U.S. 668, 53 USPQ 6 (1942).

Form paragraph 14.22.01 may be used where new matter has been added anywhere in "the application for reissue" as prohibited by 35 U.S.C. 251.

¶ *14.22.01 Rejection, 35 U.S.C. 251, New Matter*

Claim **[1]** rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: **[2]**

Examiner Note:

1. In bracket 2, fill in the applicable page and line numbers and provide an explanation of your position, as appropriate.

2. A rejection under 35 U.S.C. 112, first paragraph, should also be made if the new matter is added to the claims or is added to the specification and affects the claims. If new matter is added to the specification and does not affect the claims, an objection should be made based upon 35 U.S.C. 132 using form paragraph 7.28.

1412 Content of Claims

The content of claims in a reissue application is somewhat limited, as is indicated in MPEP § 1412.01 through MPEP § 1412.03.

1412.01 Reissue Claims Must Be for Same General Invention [R-7]

The reissue claims must be for the same invention as that **disclosed** as being the invention in the original patent, as required by 35 U.S.C. 251. **The entire disclosure, not just the claim(s), is considered in determining what the patentee objectively intended as his or her invention. The proper test as to whether reissue claims are for the same invention as that disclosed as being the invention in the original patent is "an essentially factual inquiry confined to the objective intent manifested by the **original patent**." *In re Amos*, 953 F.2d 613, 618, 21 USPQ2d 1271, 1274 (Fed. Cir. 1991) (quoting *In re Rowand,* 526 F.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975)) (emphasis added). See also *In re Mead*, 581 F.2d 257, 198 USPQ 412 (CCPA 1978). The "original patent" requirement of 35 U.S.C. 251 must be understood in light of *In re Amos, supra,* where the Court of Appeals for the Federal Circuit stated:

> We conclude that, under both *Mead* and *Rowand*, a claim submitted in reissue may be rejected under the "original patent" clause if the original specification demonstrates, to one skilled in the art, an absence of disclosure sufficient to indicate that a patentee could have claimed the subject matter. Merely finding that the subject matter was "not originally claimed, not an object of the original patent, and not depicted in the drawing," does not answer the essential inquiry under the "original patent" clause of § 251, which is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees. In short, the absence of an "intent," even if objectively evident from the earlier claims, the drawings, or the original objects

Chapter 1400 Correction of Patents

1400.01 Introduction
1401 Reissue
1402 Grounds for Filing
1403 Diligence in Filing
1404 Submission of Papers Where Reissue Patent Is in Litigation
1405 Reissue and Patent Term
1406 Citation and Consideration of References Cited in Original Patent
1410 Content of Reissue Application
1410.01 Reissue Applicant, Oath or Declaration, and Consent of all Assignees
1411 Form of Specification
1411.01 Certificate of Correction or Disclaimer in Original Patent
1411.02 New Matter
1412 Content of Claims
1412.01 Reissue Claims Must Be for Same General Invention
1412.02 Recapture of Canceled Subject Matter
1412.03 Broadening Reissue Claims
1412.04 Correction of Inventorship
1413 Drawings
1414 Content of Reissue Oath/Declaration
1414.01 Supplemental Reissue Oath/ Declaration
1415 Reissue Application and Issue Fees
1415.01 Maintenance Fees on the Original Patent
1416 No Physical Surrender of Original Patent
1417 Claim for Benefit Under 35 U.S.C. 119(a)-(d)
1418 Notification of Prior/Concurrent Proceedings and Decisions Thereon, and of Information Known To Be Material to Patentability
1430 Reissue Files Open to the Public and, Notice of Filing Reissue Announced in, Official Gazette
1440 Examination of Reissue Application
1441 Two-Month Delay Period
1441.01 Protest in Reissue Applications
1442 Special Status
1442.01 Litigation-Related Reissues
1442.02 Concurrent Litigation
1442.03 Litigation Stayed
1442.04 Litigation Involving Patent
1442.05 Court Ordered Filing of Reissue Application
1443 Initial Examiner Review
1444 Review of Reissue Oath/Declaration
1445 Reissue Application Examined in Same Manner as Original Application
1448 Fraud, Inequitable Conduct, or Duty of Disclosure Issues
1449 Protest Filed in Reissue Where Patent Is in Interference
1449.01 Concurrent Office Proceedings
1449.02 Interference in Reissue
1450 Restriction and Election of Species Made in Reissue Application
1451 Divisional Reissue Applications; Continuation Reissue Applications Where the Parent is Pending
1452 Request for Continued Examination of Reissue Application
1453 Amendments to Reissue Applications
1454 Appeal Brief
1455 Allowance and Issue
1456 Reissue Review
1457 Design Reissue Applications and Patents
1460 Effect of Reissue
1470 Public Access of Reissue Applications
1480 Certificates of Correction — Office Mistake
1480.01 Expedited Issuance of Certificates of Correction - Error Attributable to Office
1481 Certificates of Correction - Applicant's Mistake
1481.01 Correction of Assignees' Names
1481.02 Correction of Inventors' Names
1481.03 Correction of 35 U.S.C. 119 and 35 U.S.C. 120 Benefits
1485 Handling of Request for Certificates of Correction
1490 Disclaimers

1400.01 Introduction [R-2]

A patent may be corrected or amended in four ways, namely:

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The first three ways are discussed in this chapter while the fourth way (reexamination) is discussed in MPEP Chapter 2200> for *ex parte* reexamination and MPEP Chapter 2600 for *inter partes* reexamination<.

1401 Reissue [R-3]

35 U.S.C. 251 Reissue of defective patents.

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a

the patent have been properly incorporated into the reissue application.

Certificate of Correction changes and disclaimer of claim(s) under 37 CFR 1.321(a) should be made without using underlining or brackets. *>Because< these are >retroactively a< part of the original patent and *>are< made before the reissue **>application will issue as a patent, they must< show up in the printed reissue patent document as part of the original patent, i.e., not in italics or bracketed. >If the changes are submitted improperly with underlining and brackets, the examiner will require correction by the applicant in the form of a replacement paragraph (or paragraphs) without such markings.< If the changes are extensive**, a clean copy of the specification with the Certificate of Correction changes in it may be *>required< by the examiner >after consulting with his/her supervisor<. **>For< the clean copy >of the specification< to be entered as a substitute specification, the reissue applicant must file a grantable petition under 37 CFR 1.183 for waiver of 37 CFR 1.125(d) and 37 CFR 1.173(a)(1). The examiner's *>requirement< for the clean copy will generally serve as sufficient basis for granting the petition.

1411.02 New Matter

New matter, that is, matter not present in the patent sought to be reissued, is excluded from a reissue application in accordance with 35 U.S.C. 251.

The claims in the reissue application must be for subject matter which the applicant had the right to claim in the original patent. *Any* change in the patent made via the reissue application should be checked to ensure that it does not introduce new matter. Note that new matter may exist by virtue of the omission of a feature or of a step in a method. See *United States Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.,* 315 U.S. 668, 53 USPQ 6 (1942).

Form paragraph 14.22.01 may be used where new matter has been added anywhere in "the application for reissue" as prohibited by 35 U.S.C. 251.

¶ *14.22.01 Rejection, 35 U.S.C. 251, New Matter*

Claim **[1]** rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: **[2]**

Examiner Note:

1. In bracket 2, fill in the applicable page and line numbers and provide an explanation of your position, as appropriate.

2. A rejection under 35 U.S.C. 112, first paragraph, should also be made if the new matter is added to the claims or is added to the specification and affects the claims. If new matter is added to the specification and does not affect the claims, an objection should be made based upon 35 U.S.C. 132 using form paragraph 7.28.

1412 Content of Claims

The content of claims in a reissue application is somewhat limited, as is indicated in MPEP § 1412.01 through MPEP § 1412.03.

1412.01 Reissue Claims Must Be for Same General Invention [R-7]

The reissue claims must be for the same invention as that **disclosed** as being the invention in the original patent, as required by 35 U.S.C. 251. **The entire disclosure, not just the claim(s), is considered in determining what the patentee objectively intended as his or her invention. The proper test as to whether reissue claims are for the same invention as that disclosed as being the invention in the original patent is "an essentially factual inquiry confined to the objective intent manifested by the **original patent**." *In re Amos*, 953 F.2d 613, 618, 21 USPQ2d 1271, 1274 (Fed. Cir. 1991) (quoting *In re Rowand,* 526 F.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975)) (emphasis added). See also *In re Mead*, 581 F.2d 257, 198 USPQ 412 (CCPA 1978). The "original patent" requirement of 35 U.S.C. 251 must be understood in light of *In re Amos, supra,* where the Court of Appeals for the Federal Circuit stated:

> We conclude that, under both *Mead* and *Rowand*, a claim submitted in reissue may be rejected under the "original patent" clause if the original specification demonstrates, to one skilled in the art, an absence of disclosure sufficient to indicate that a patentee could have claimed the subject matter. Merely finding that the subject matter was "not originally claimed, not an object of the original patent, and not depicted in the drawing," does not answer the essential inquiry under the "original patent" clause of § 251, which is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees. In short, the absence of an "intent," even if objectively evident from the earlier claims, the drawings, or the original objects

of the invention is simply not enough to establish that the new claims are not drawn to the invention disclosed in the original patent.

953 F.2d at 618-19, 21 USPQ2d at 1275. Claims presented in a reissue application are considered to satisfy the requirement of **35 U.S.C. 251** that the claims be "for the invention disclosed in the original patent" where:

(A) the claims presented in the reissue application are described in the original patent specification and enabled by the original patent specification such that **35 U.S.C. 112** first paragraph is satisfied; and

(B) nothing in the original patent specification indicates an intent not to claim the subject matter of the claims presented in the reissue application.

The presence of some disclosure (description and enablement) in the original patent should evidence that applicant intended to claim or that applicant considered the material now claimed to be his or her invention.

The original patent specification would indicate an intent not to claim the subject matter of the claims presented in the reissue application in a situation analogous to the following:

The original patent specification discloses that composition X is not suitable (or not satisfactory) for molding an item because composition X fails to provide quick drying. >The patent issues with claims directed only to composition Y.< After the patent issues, it is found that composition X would be desirable for the molding in spite of the failure to provide quick drying, because of some other newly recognized benefit from composition X. *>The addition of a< claim to composition X or a method of use thereof would not be permitted in a reissue application, because the original patent specification contained an explicit statement of intent *not* to claim composition X or a method of use thereof.

>One should understand<, however, >that< the mere failure to claim a disclosed embodiment in the original patent (absent an explicit statement in the original patent specification of unsuitability of the embodiment) would **not be grounds for prohibiting a claim to that embodiment in the reissue.

FAILURE TO TIMELY FILE A DIVISIONAL APPLICATION PRIOR TO ISSUANCE OF ORIGINAL PATENT

Where a restriction >(or an election of species)< requirement was made in an application and applicant permitted the elected invention to issue as a patent without * filing * a divisional application on the non-elected invention(s), the non-elected invention(s) cannot be recovered by filing a reissue application. A reissue applicant's failure to timely file a divisional application covering the non-elected invention(s) in response to a restriction >(or an election of species)< requirement is not considered to be error causing a patent granted on the elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Accordingly, **>this< is not correctable by reissue of the original patent under 35 U.S.C. 251. *In re Watkinson*, 900 F.2d 230, 14 USPQ2d 1407 (Fed. Cir. 1990); *In re Orita*, 550 F.2d 1277, 1280, 193 USPQ 145, 148 (CCPA 1977). See also *In re Mead*, 581 F.2d 251, 198 USPQ 412 (CCPA 1978). In this situation, the reissue claims should be rejected under 35 U.S.C. 251 for lack of defect in the original patent and lack of error in obtaining the original patent. Compare with *In re Doyle*, 293 F.3d 1355, 63 USPQ2d 1161 (Fed. Cir. 2002) where the court permitted the patentee to file a reissue application to present a so-called linking claim, a claim broad enough to read on or link the invention elected (and patented) together with the invention not elected. The non-elected invention(s) were inadvertently not filed as a divisional application.

1412.02 Recapture of Canceled Subject Matter [R-9]

A reissue will not be granted to "recapture" claimed subject matter which was surrendered in an application to obtain the original patent. *North American Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 75 USPQ2d 1545 (Fed. Cir. 2005), Pannu v. Storz Instruments Inc., 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984); *In re Wadlinger*, 496 F.2d 1200, 181 USPQ 826 (CCPA 1974); *In re Richman*, 409 F.2d 269, 276, 161 USPQ 359, 363-364 (CCPA 1969); *In re Willingham*, 282 F.2d 353, 127 USPQ 211 (CCPA 1960).

I. THREE STEP TEST FOR RECAPTURE:

In *Clement*, 131 F.3d at 1468-70, 45 USPQ2d at 1164-65, the Court of Appeals for the Federal Circuit set forth a three step test for recapture analysis. In *North American Container*, 415 F.3d at 1349, 75 USPQ2d at 1556, the court restated this test as follows:

We apply the recapture rule as a three-step process:

Chapter 1400 Correction of Patents

1400.01 Introduction
1401 Reissue
1402 Grounds for Filing
1403 Diligence in Filing
1404 Submission of Papers Where Reissue Patent Is in Litigation
1405 Reissue and Patent Term
1406 Citation and Consideration of References Cited in Original Patent
1410 Content of Reissue Application
1410.01 Reissue Applicant, Oath or Declaration, and Consent of all Assignees
1411 Form of Specification
1411.01 Certificate of Correction or Disclaimer in Original Patent
1411.02 New Matter
1412 Content of Claims
1412.01 Reissue Claims Must Be for Same General Invention
1412.02 Recapture of Canceled Subject Matter
1412.03 Broadening Reissue Claims
1412.04 Correction of Inventorship
1413 Drawings
1414 Content of Reissue Oath/Declaration
1414.01 Supplemental Reissue Oath/ Declaration
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1415.01 Maintenance Fees on the Original Patent
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1417 Claim for Benefit Under 35 U.S.C. 119(a)-(d)
1418 Notification of Prior/Concurrent Proceedings and Decisions Thereon, and of Information Known To Be Material to Patentability
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1441.01 Protest in Reissue Applications
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1442.03 Litigation Stayed
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1443 Initial Examiner Review
1444 Review of Reissue Oath/Declaration
1445 Reissue Application Examined in Same Manner as Original Application
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1455 Allowance and Issue
1456 Reissue Review
1457 Design Reissue Applications and Patents
1460 Effect of Reissue
1470 Public Access of Reissue Applications
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1480.01 Expedited Issuance of Certificates of Correction - Error Attributable to Office
1481 Certificates of Correction - Applicant's Mistake
1481.01 Correction of Assignees' Names
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Office action, and the examiner will set forth the reasons for same.

1414 Content of Reissue Oath/Declaration [R-9]

37 CFR 1.175 Reissue oath or declaration.

(a) The reissue oath or declaration in addition to complying with the requirements of § 1.63, must also state that:(1) The applicant believes the original patent to be wholly or partly inoperative or invalid by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than the patentee had the right to claim in the patent, stating at least one error being relied upon as the basis for reissue; and

(2) All errors being corrected in the reissue application up to the time of filing of the oath or declaration under this paragraph arose without any deceptive intention on the part of the applicant.

(b) (1) For any error corrected, which is not covered by the oath or declaration submitted under paragraph (a) of this section, applicant must submit a supplemental oath or declaration stating that every such error arose without any deceptive intention on the part of the applicant. Any supplemental oath or declaration required by this paragraph must be submitted before allowance and may be submitted:(i) With any amendment prior to allowance; or

(ii) In order to overcome a rejection under 35 U.S.C. 251 made by the examiner where it is indicated that the submission of a supplemental oath or declaration as required by this paragraph will overcome the rejection.

(2) For any error sought to be corrected after allowance, a supplemental oath or declaration must accompany the requested correction stating that the error(s) to be corrected arose without any deceptive intention on the part of the applicant.

(c) Having once stated an error upon which the reissue is based, as set forth in paragraph (a)(1), unless all errors previously stated in the oath or declaration are no longer being corrected, a subsequent oath or declaration under paragraph (b) of this section need not specifically identify any other error or errors being corrected.

(d) The oath or declaration required by paragraph (a) of this section may be submitted under the provisions of § 1.53(f).

(e) The filing of any continuing reissue application which does not replace its parent reissue application must include an oath or declaration which, pursuant to paragraph (a)(1) of this section, identifies at least one error in the original patent which has not been corrected by the parent reissue application or an earlier reissue application. All other requirements relating to oaths or declarations must also be met.

The reissue oath/declaration is an essential part of a reissue application and must be filed with the application, or within the time period set under 37 CFR 1.53(f) along with the required surcharge as set forth in 37 CFR 1.16(f) in order to avoid abandonment.

The question of the sufficiency of the reissue oath/declaration filed under 37 CFR 1.175 must in each case be reviewed and decided personally by the primary examiner.

Reissue oaths or declarations must contain the following:

(A) A statement that the applicant believes the original patent to be wholly or partly inoperative or invalid—(1) by reason of a defective specification or drawing, or

(2) by reason of the patentee claiming more or less than patentee had the right to claim in the patent;

(B) A statement of at least one error which is relied upon to support the reissue application, *i.e.*, as the basis for the reissue;

(C) A statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant; and

(D) The information required by 37 CFR 1.63.

These elements will now be discussed:

I. A STATEMENT THAT THE APPLICANT BELIEVES THE ORIGINAL PATENT TO BE WHOLLY OR PARTLY INOPERATIVE OR INVALID BY REASON OF A DEFECTIVE SPECIFICATION OR DRAWING, OR BY REASON OF THE PATENTEE CLAIMING MORE OR LESS THAN PATENTEE HAD THE RIGHT TO CLAIM IN THE PATENT.

In order to satisfy this requirement, a declaration can state as for example:

1. "Applicant believes the original patent to be partly inoperative or invalid by reason of a defective specification or drawing."

2. "Applicant believes the original patent to be partly inoperative or invalid by reason of the patentee claiming more than patentee had a right to claim in the patent."

3. "Applicant believes the original patent to be partly inoperative or invalid by reason of the patentee claiming less than patentee had a right to claim in the patent."

**

It should be noted that the reissue oath/declaration must also satisfy the requirement for a statement of at least one

error being relied upon as the basis for reissue, in the manner set forth in subsection II. below.

>Even though only one error upon which reissue is based needs to be described in the reissue oath/declaration, if PTO/SB/51 or PTO/SB/52 form is used, applicant needs to check the appropriate box(es) on the form identifying each of the reasons why the patent is wholly or partly inoperative or invalid. Even if a PTO form is not used, applicant needs to state all the reasons why the patent is wholly or partly inoperative or invalid in the reissue oath/declaration.<

Form paragraph 14.01 may be used where the reissue oath/declaration does not provide the required statement as to applicant's belief that the original patent is wholly or partly inoperative or invalid.

**

>

¶ *14.01 Defective Reissue Oath/Declaration, 37 CFR 1.175(a)(1) - No Statement of Defect in the Patent*

The reissue oath/declaration filed with this application is defective because it fails to contain the statement(s) required under **37 CFR 1.175(a)(1)** as to applicant's belief that the original patent is wholly or partly inoperative or invalid. See **37 CFR 1.175(a)(1)** and see **MPEP § 1414**. **[1]**

Examiner Note:

1. Use this form paragraph when applicant: (a) fails to allege that the original patent is inoperative or invalid and/or (b) fails to state the reason of a defective specification or drawing, or of patentee claiming more or less than patentee had the right to claim in the patent. In bracket 1, point out the specific defect to applicant by using the language of (a) and/or (b), as it is appropriate.

2. Form paragraph 14.14 must follow this form paragraph.

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II. A STATEMENT OF AT LEAST ONE ERROR WHICH IS RELIED UPON TO SUPPORT THE REISSUE APPLICATION (I.E., THE BASIS FOR THE REISSUE).

(A) A reissue applicant must acknowledge the existence of an error in the specification, drawings, or claims, which error causes the original patent to be defective. *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984). A change or departure from the original specification or claims represents an "error" in the original patent under **35 U.S.C. 251**. See MPEP § **1402** for a discussion of grounds for filing a reissue that may constitute the "error" required by **35 U.S.C. 251**. Not all changes with respect to the patent constitute the "error" required by **35 U.S.C. 251**.> It is noted that an error to be corrected under 35 U.S.C. **251** may be the addition of a claim or claims that is/are narrower in scope than the existing patent claims, without any narrowing of the existing patent claims. See *In re Tanaka*, 640 F.3d 1246, 1251, 98 USPQ2d 1331, 1334 (Fed. Cir. 2011).<

(B) Applicant need only specify in the reissue oath/declaration one of the errors upon which reissue is based. Where applicant specifies one such error, this requirement of a reissue oath/declaration is satisfied. Applicant may specify more than one error.Where more than one error is specified in the oath/declaration and some of the designated "errors" are found to not be "errors" under **35 U.S.C. 251**, any remaining error which is an error under **35 U.S.C. 251** will still support the reissue.The "at least one error" which is relied upon to support the reissue application must be set forth in the oath/declaration. It is not necessary, however, to point out how (or when) the error arose or occurred. Further, it is not necessary to point out how (or when) the error was discovered. If an applicant chooses to point out these matters, the statements directed to these matters will not be reviewed by the examiner, and the applicant should be so informed in the next Office action. All that is needed for the oath/declaration statement as to error is the identification of "at least one error" relied upon.In identifying the error, it is sufficient that the reissue oath/declaration identify a single word, phrase, or expression in the specification or in an original claim, and how it renders the original patent wholly or partly inoperative or invalid. The corresponding corrective action which has been taken to correct the original patent need not be identified in the oath/declaration. If the initial reissue oath/declaration "states at least one error" in the original patent, and, *in addition*, recites the specific corrective action taken in the reissue application, the oath/declaration would be considered acceptable, even though the corrective action statement is not required.

(C) It is not sufficient for an oath/declaration to merely state "this application is being filed to correct errors in the patent which may be noted from the changes made in the disclosure." Rather, the oath/declaration must specifically identify an error. In addition, it is not sufficient to merely reproduce the claims with brackets and underlining and state that such will identify the error. See *In re Constant*, 827 F.2d 728, 729, 3 USPQ2d 1479 (Fed. Cir.), *cert. denied*, 484 U.S. 894 (1987). Any error in the claims must be identified by reference to the specific claim(s) and the specific claim language wherein lies the error.A statement >in the oath/declaration < of "…failure to include a claim directed to…" and then *>reciting all the limitations of< a newly added claim, would not be considered a sufficient "error" statement because applicant has not pointed out what the other claims lacked that the newly added claim has, or vice versa. Such a statement would be no better than saying

in the reissue oath or declaration that "this application is being filed to correct errors in the patent which may be noted from the change made by adding new claim 10." In both cases, the error has not been identified.Likewise, a statement of the error as "…the inclusion of claims 3-5 which were unduly broad…" and then canceling claims 3-5, would not be considered a sufficient "error" statement because applicant has not pointed out what the canceled claims lacked that the remaining claims contain. The statement of what the remaining claims contain need not identify specific limitations, but rather may provide a general identification, such as "Claims 3-5 did not provide for any of the tracking mechanisms of claims 6-12, nor did they provide an attachment mechanism such as those in claims 1-2 and 9-16."

(D) Where a continuation reissue application is filed with a copy of the reissue oath/declaration from the parent reissue application, and the parent reissue application is not to be abandoned, the reissue oath/declaration should be accepted by the Office of Initial Patent Examination without further evaluation, because it is an oath/declaration, albeit improper under 35 U.S.C. **251**. The examiner should, however, reject the claims of the continuation reissue application under 35 U.S.C. **251** as being based on an oath/declaration that does not identify an error being corrected by the continuation reissue application, and should require a new oath/declaration. 37 CFR **1.175**(e) states that "the filing of any continuing reissue application which does not replace its parent reissue application must include an oath or declaration, which pursuant to [37 CFR **1.175**(a)(1)], identifies at least one error in the original patent which has not been corrected by the parent reissue application or an earlier reissue application." One of form paragraphs 14.01.01 through 14.01.03 may be used.Where a continuation reissue application is filed with a copy of the reissue oath/declaration from the parent reissue application, and the parent reissue application is, or will be abandoned, the copy of the reissue oath/declaration should be accepted by the Office of Patent Application Processing (OPAP), and the examiner should check to ensure that the oath/declaration identifies an error which is still being corrected in the continuation application. If a preliminary amendment was filed with the continuation reissue application, the examiner should check for the need of a supplemental reissue oath/declaration. Pursuant to 37 CFR **1.175** (b)(1), for any error corrected via the preliminary amendment which is not covered by the oath or declaration submitted in the parent reissue application, applicant must submit a supplemental oath/declaration stating that such error arose without any deceptive intention on the part of the applicant. See MPEP § **1414.01**.Where a divisional reissue application is filed with a copy of the reissue oath/declaration from the parent reissue application, the reissue oath/declaration should be accepted by OPAP, because it is an oath/declaration, though it may be improper under 35 U.S.C. **251** . The examiner should check the copy of the oath/declaration to ensure that it identifies an error being corrected by the divisional reissue application. The copy of the oath/declaration from the parent reissue application may or may not cover an error being corrected by the divisional reissue application because the divisional reissue application is (by definition) directed to a new invention. If it does not, the examiner should reject the claims of the divisional reissue application under 35 U.S.C. **251** as being based on an oath/declaration that does not identify an error being corrected by the divisional reissue application, and require a new oath/declaration. If the copy of the reissue oath/declaration from the parent reissue application does in fact cover an error being corrected in the divisional reissue application, no such rejection should be made. However, because a new invention is being added by the filing of the divisional reissue application, a supplemental reissue oath/declaration pursuant to 37 CFR **1.175** (b)(1) will be required. See MPEP § **1414.01**.Form paragraph 14.01.01 may be used where the reissue oath/declaration does not identify an error.

¶ *14.01.01 Defective Reissue Oath/Declaration, 37 CFR 1.175(a)(1) - No Statement of a Specific Error*

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See **37 CFR 1.175(a)**(1) and **MPEP § 1414**.

Examiner Note:

1. Use this form paragraph when the reissue oath or declaration does not contain any statement of an error which is relied upon to support the reissue application.

2. This form paragraph can be used where the reissue oath or declaration does not even mention error. It can also can be used where the reissue oath or declaration contains some discussion of the concept of error but never in fact identifies a specific error to be relied upon. For example, it is not sufficient for an oath or declaration to merely state "this application is being filed to correct errors in the patent which may be noted from the changes made in the disclosure."

3. Form paragraph 14.14 must follow this form paragraph.

Where the reissue oath/declaration does identify an error or errors, the oath/declaration must be checked carefully to ensure that at least one of the errors identified is indeed an "error" which will support the filing of a reissue, i.e., an "error" that will provide grounds for reissue of the patent. See MPEP § **1402**. If the error identified in the oath/declaration is not an appropriate error upon which a reissue can be based, then the oath/declaration must be indicated to be defective in the examiner's Office action.

Form paragraphs 14.01.02 and 14.01.03 may be used where the reissue oath/declaration fails to provide at least one error upon which a reissue can be based.

¶ *14.01.02 Defective Reissue Oath/Declaration, 37 CFR 1.175(a)(1)-The Identified "Error" Is Not Appropriate Error*

The reissue oath/declaration filed with this application is defective because the error which is relied upon to support the reissue application is not an error upon which a reissue can be based. See **37 CFR 1.175(a)**(1) and **MPEP § 1414**.

Examiner Note:

1. Use this form paragraph when the reissue oath/declaration identifies only one error which is relied upon to support the reissue application, and that one error is not an appropriate error upon which a reissue can be based.

2. Form paragraph 14.14 must follow this form paragraph.

¶ *14.01.03 Defective Reissue Oath/Declaration, 37 CFR 1.175(a)(1) - Multiple Identified "Errors" Not Appropriate Errors*

The reissue oath/declaration filed with this application is defective because none of the errors which are relied upon to support the reissue application are errors upon which a reissue can be based. See **37 CFR 1.175(a)**(1) and **MPEP § 1414**.

Examiner Note:

1. Use this form paragraph when the reissue oath/declaration identifies more than one error relied upon to support the reissue application, and none of the errors are appropriate errors upon which a reissue can be based.

2. Note that if the reissue oath/declaration identifies more than one error relied upon, and at least one of the errors is an error upon which reissue can be based, this form paragraph should not be used, despite the additional reliance by applicant on "errors" which do not support the reissue. Only one appropriate error is needed to support a reissue.

3. Form paragraph 14.14 must follow this form paragraph.

III. A STATEMENT THAT ALL ERRORS WHICH ARE BEING CORRECTED IN THE REISSUE APPLICATION UP TO THE TIME OF SIGNING OF THE OATH/DECLARATION AROSE WITHOUT ANY DECEPTIVE INTENTION ON THE PART OF THE APPLICANT.

In order to satisfy this requirement, the following statement may be included in an oath or declaration:

> "All errors >corrected <in the present reissue application up to the time of signing of this oath/declaration, or errors which are being corrected by a paper filed concurrently with this oath/declaration which correction of errors I/we have reviewed, arose without any deceptive intention on the part of the applicant."

Nothing more is required. The examiner will determine only whether the reissue oath/declaration contains the required averment; the examiner will not make any comment as to whether it appears that there was in fact deceptive intention (see MPEP § **2022.05**). It is noted that a reissue oath/declaration will not be effective for any errors which are corrected by a filing made after the execution of the reissue oath/declaration, unless it is clear from the record that the parties executing the document were aware of the nature of the correction when they executed the document. Further, a reissue oath/declaration with an early date of execution cannot be filed after a correction made later in time, to cover the correction made after the execution date. This is so, even if the reissue oath/declaration states that *all errors up to the filing of the oath/declaration* arose without any deceptive intention on the part of the applicant.

Form paragraph 14.01.04 may be used where the reissue oath/declaration does not provide the required statement as to "without any deceptive intention on the part of the applicant."

¶ *14.01.04 Defective Reissue Oath/Declaration, 37 CFR 1.175- Lack of Statement of "Without Any Deceptive Intention"*

The reissue oath/declaration filed with this application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant. See **37 CFR 1.175** and **MPEP § 1414**.

Examiner Note:

1. Use this form paragraph when the reissue oath/declaration does not contain the statement required by **37 CFR 1.175** that all errors being corrected in the reissue application arose without any deceptive intention on the part of the applicant.

Chapter 1400 Correction of Patents

1400.01 Introduction
1401 Reissue
1402 Grounds for Filing
1403 Diligence in Filing
1404 Submission of Papers Where Reissue Patent Is in Litigation
1405 Reissue and Patent Term
1406 Citation and Consideration of References Cited in Original Patent
1410 Content of Reissue Application
1410.01 Reissue Applicant, Oath or Declaration, and Consent of all Assignees
1411 Form of Specification
1411.01 Certificate of Correction or Disclaimer in Original Patent
1411.02 New Matter
1412 Content of Claims
1412.01 Reissue Claims Must Be for Same General Invention
1412.02 Recapture of Canceled Subject Matter
1412.03 Broadening Reissue Claims
1412.04 Correction of Inventorship
1413 Drawings
1414 Content of Reissue Oath/Declaration
1414.01 Supplemental Reissue Oath/ Declaration
1415 Reissue Application and Issue Fees
1415.01 Maintenance Fees on the Original Patent
1416 No Physical Surrender of Original Patent
1417 Claim for Benefit Under 35 U.S.C. 119(a)-(d)
1418 Notification of Prior/Concurrent Proceedings and Decisions Thereon, and of Information Known To Be Material to Patentability
1430 Reissue Files Open to the Public and, Notice of Filing Reissue Announced in, Official Gazette
1440 Examination of Reissue Application
1441 Two-Month Delay Period
1441.01 Protest in Reissue Applications
1442 Special Status
1442.01 Litigation-Related Reissues
1442.02 Concurrent Litigation
1442.03 Litigation Stayed
1442.04 Litigation Involving Patent
1442.05 Court Ordered Filing of Reissue Application
1443 Initial Examiner Review
1444 Review of Reissue Oath/Declaration
1445 Reissue Application Examined in Same Manner as Original Application
1448 Fraud, Inequitable Conduct, or Duty of Disclosure Issues
1449 Protest Filed in Reissue Where Patent Is in Interference
1449.01 Concurrent Office Proceedings
1449.02 Interference in Reissue
1450 Restriction and Election of Species Made in Reissue Application
1451 Divisional Reissue Applications; Continuation Reissue Applications Where the Parent is Pending
1452 Request for Continued Examination of Reissue Application
1453 Amendments to Reissue Applications
1454 Appeal Brief
1455 Allowance and Issue
1456 Reissue Review
1457 Design Reissue Applications and Patents
1460 Effect of Reissue
1470 Public Access of Reissue Applications
1480 Certificates of Correction — Office Mistake
1480.01 Expedited Issuance of Certificates of Correction - Error Attributable to Office
1481 Certificates of Correction - Applicant's Mistake
1481.01 Correction of Assignees' Names
1481.02 Correction of Inventors' Names
1481.03 Correction of 35 U.S.C. 119 and 35 U.S.C. 120 Benefits
1485 Handling of Request for Certificates of Correction
1490 Disclaimers

1400.01 Introduction [R-2]

A patent may be corrected or amended in four ways, namely:

(A) by reissue,

(B) by the issuance of a certificate of correction which becomes a part of the patent,

(C) by disclaimer, and

(D) by reexamination.

The first three ways are discussed in this chapter while the fourth way (reexamination) is discussed in MPEP Chapter 2200> for *ex parte* reexamination and MPEP Chapter 2600 for *inter partes* reexamination<.

1401 Reissue [R-3]

35 U.S.C. 251 Reissue of defective patents.

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a

C. Proper second amendment format.

Claim 1 (Twice Amended). A [cutting means] knife having a handle portion and a serrated blade portion.

Note that the second amendment must include the changes previously presented in the first amendment, i.e., [cutting means] knife, as well as the new changes presented in the second amendment, i.e., serrated.

The word bone was presented in the first amendment and is now to be deleted in the second amendment. The word "bone" is NOT to be shown in brackets in the second amendment. Rather, the word "bone" is simply omitted from the claim, because "bone" never appeared in the patent. An explanation of the deletion should appear in the remarks.

The word notched which was presented in the first amendment is replaced by the word serrated in the second amendment. The word notched is being deleted in the second amendment and did not appear in the patent; accordingly, "notched" is not shown in any form in the claim. The word serrated is being added in the second amendment, and accordingly "serrated" is added to the claim and is underlined.

In the second amendment, the deletions of "notched" and "bone" are not changes from the original patent claim text and therefore are not shown in brackets in the second amendment. In both the first and the second amendments, the entire claim is presented only with the changes from the original patent text.

VI. ADDITIONAL EXAMPLES

(A) For a reissue application, where the patent was previously reissued:As per MPEP § 1411, double underlining and double bracketing are used in the second reissue application to show amendments made relative to the first reissued patent

(B) For a reissue application, where the patent was previously reexamined and a reexamination certificate has issued for the patent:An amendment in the reissue application must be presented as if the changes made to the original patent text via the reexamination certificate are a part of the original patent. Thus, all italicized text of the reexamination certificate is presented in the amendment (made in the reissue application) without italics. Further, any text found in brackets in the reexamination certificate is omitted in the amendment (made in the reissue application). >A claim canceled by the reexamination certificate must be deleted by a direction to strike through the claim, i.e., the canceled claim(s) should be lined through, and not surrounded by brackets.<

(C) For a reissue application, where a certificate of correction has issued for the patent:An amendment in the reissue application must be presented as if the changes made to the original patent text via the certificate of correction are a part of the original patent. Thus, all text added by certificate of correction is presented in the amendment (made in the reissue application) without italics. Further, any text deleted by certificate of correction is entirely omitted in the amendment (made in the reissue application). >A claim canceled by the certificate of correction must be deleted by a direction to strike through the claim, i.e., the canceled claim(s) should be lined through, and not surrounded by brackets.<

(D) For a reissue application, where a statutory disclaimer has issued for the patent:Any claim statutorily disclaimed is no longer in the patent, and such a claim cannot be amended. *> A disclaimed claim must be deleted by a direction to strike through the claim, i.e., the< statutorily disclaimed claim(s) should be lined through, and not surrounded by brackets.

1454 Appeal Brief [R-9]

The requirements for an appeal brief are set forth in 37 CFR 41.37 and MPEP § 1206, and they apply to a reissue application in the same manner that they apply to a non-reissue application. There is, however, a difference in practice as to presentation of the copy of the claims in the appeal brief for a reissue application. The claims on appeal presented in an appeal brief for a reissue application should include all underlining and bracketing necessary to reflect the changes made to the patent claims during the prosecution of the reissue application. In addition, any new claims added in the reissue application should be completely underlined.

1455 Allowance and Issue [R-9]

I. ISSUE CLASSIFICATION SHEET

For IFW reissue applications:

The examiner completes the Issue Classification sheet in the same manner as for a non-reissue application. In addition, a copy of the "Final SPRE Review" form must also be completed.

II. CHANGES TO THE ORIGINAL PATENT

The specifications of reissue patents will be printed in such a manner as to show the changes over the original patent text by enclosing any material omitted by the reissue in heavy brackets [ ] and printing material added

by the reissue in *italics* . 37 CFR 1.173 (see MPEP § 1411) requires the specification of a reissue application to be presented in a specified form, specifically designed to facilitate this different manner of printing, as well as for other reasons.

The printed reissue patent specification will carry the following heading, which will be added by the Publishing Division of the Office of Patent Publication:

> "Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue."

The examiners should see that the specification is in proper form for printing. Examiners should carefully check the entry of all amendments to ensure that the changes directed by applicant will be accurately printed in any reissue patent that may ultimately issue. Matter appearing in the original patent which is omitted by reissue should be enclosed in brackets, while matter added by reissue should be underlined.

Any material added by amendment in the reissue application (as underlined text) which is later canceled should be crossed through, *and not bracketed*. Material canceled from the original patent should be enclosed in brackets, *and not lined through.*

All the claims of the original patent should appear in the reissue patent, with canceled patent claims being enclosed in brackets.

III. CLAIM NUMBERING

No renumbering of the original patent claims is permitted, even if the dependency of a dependent patent claim is changed by reissue so that it is to be dependent on a subsequent higher numbered claim.

When a dependent claim in a reissue application depends upon a claim which has been canceled, and the dependent claim is not thereafter made dependent upon a pending claim, such a dependent claim must be rewritten in independent form.

New claims added during the prosecution of the reissue application should follow the number of the highest numbered patent claim and should be completely underlined to indicate they are to be printed in italics on the printed patent. Often, as a result of the prosecution and examination, some new claims are canceled while other new claims remain. When the reissue application is allowed, any claims remaining which are additional to the patent claims (i.e., claims added via the reissue application) should be renumbered in sequence starting with the number next higher than the number of the last claim in the original patent (the printed patent). Therefore, the number of claims allowed will not necessarily correspond to the number of the last claim in the reissue application, as allowed. The number of claims appearing in the "Total Claims Allowed" box on the Issue Classification sheet at the time of allowance should be consistent with the number of claims indicated as allowable on the Notice of Allowability (Form PTOL-37).

IV. CLAIM DESIGNATED FOR PRINTING

At least one claim of an allowable reissue application must be designated for printing in the *Official Gazette.* Whenever at least one claim has been amended or added in the reissue, the claim (claims) designated for printing must be (or include) a claim which has been changed or added by the reissue. A canceled claim is not to be designated as the claim for the *Official Gazette.*

If there is no change in the claims of the allowable reissue application (i.e., when they are the same as the claims of the original patent) or, if the only change in the claims is the cancellation of claims, then the most representative pending *allowed* claim is designated for printing in the *Official Gazette.*

V. PROVIDING PROPER FORMAT

Where a reissue application has not been prepared in the above-indicated manner, the examiner may obtain from the applicant a clean copy of the reissue specification prepared in the indicated form, or a proper submission of a previously improperly submitted amendment. However, if the deletions from the original patent are small, the reissue application can be prepared for issue by putting the bracketed inserts at the appropriate places and suitably numbering the added claims.

When applicant submits a clean copy of the reissue specification, or a proper submission of a previous improper amendment, a supplemental reissue declaration should **not** be provided to address this submission, because the correction of format does not correct a 35 U.S.C. 251 error in the patent.

VI. PARENT APPLICATION DATA

All parent application data on the bibliographic data sheet of the original patent file (or front face of the original

patent file wrapper if the original patent is a paper file) should be present on the bibliographic data sheet of the reissue application.

It sometimes happens that the reissue is a continuation reissue application of another reissue application, and there is also original-patent parent application data. The examiner should ensure that the parent application data on the original patent is properly combined with the parent application data of the reissue, in the text of the specification and on the bibliographic data sheet. The combined statement as to parent application data should be checked carefully for proper bracketing and underlining.

VII. REFERENCES CITED AND PRINTED

**>The examiner should list on a PTO-892 form any reference that was cited during the original prosecution of the patent which is again cited/applied in the reissue application.< It is noted that the Office will not print in the reissue patent "References Cited" section any reference cited in the patent but not again cited in the reissue application. >Accordingly, should an applicant wish to ensure that all of the references which were cited in the original patent are cited in the reissue application, an information disclosure statement (IDS) in compliance with 37 CFR 1.97 and 1.98 should be filed in the reissue application.< A patent cannot be reissued solely for the purpose of adding citations of additional prior art.

VIII. EXAMINER'S AMENDMENT AND SUPPLEMENTAL DECLARATION

When it is necessary to amend the reissue application in order to place the application in condition for allowance, the examiner may:

(A) request that applicant provide the amendments (e.g., by facsimile transmission or by hand-carry); or

(B) make the amendments, with the applicant's approval, by a formal examiner's amendment.

If the changes are made by a formal examiner's amendment, the *entire* paragraph(s) or claim(s) being amended need not be presented in rewritten form for any deletions or additions. Changes to the specification including the claims of an application made by the Office in an examiner's amendment may be made by specific instructions to insert or delete subject matter set forth in the examiner's amendment by identifying the precise point in the specification or the claim(s) where the insertion or deletion is to be made. 37 CFR 1.121(g).

If it is necessary to amend a claim or the specification in order to correct an "error" under 35 U.S.C. 251 and thereby place the application in condition for allowance, then a supplemental oath or declaration will be required. See MPEP § 1444. The examiner should telephone applicant and request the supplemental oath or declaration, which must be filed before the application can be counted as an allowance.

IX. FINAL REVIEW OF THE REISSUE APPLICATION BY THE EXAMINER

Before forwarding a reissue application to the Technology Center (TC) Special Program Examiner (SPRE) or appropriate Quality Assurance Specialist (QAS) for final review, the examiner should complete and initial an Examiner Reissue Checklist. A copy of the checklist should be available from the SPRE/QAS or from the Paralegal Specialist of the TC.

1456 Reissue Review [R-7]

All reissue applications are monitored and reviewed in the Technology Centers (TCs) by the Office of TC Special Program Examiners >or appropriate Quality Asurance Specialist (QAS)< (which includes TC >SPREs/QASs<, paralegals or other technical support who might be assigned as backup) at several stages during the prosecution. The review by the Office of the TC *>SPREs/QASs< is made to check that practice and procedure unique to reissue has been carried out for the reissue application. In addition **, a patentability review is made in a sample of reissue applications by the TC **>QAS< in the manner previously carried out by the former Office of Patent Quality Review. In order to ensure that *>SPREs/QASs< are aware of the reissue applications in their TCs, a pair of terminal-specific PALM flags have been created which must be set by the *>SPRE/QAS< before certain PALM transactions can be completed. First, when a new reissue application enters the TC, a *>SPRE/QAS< must set a PALM "flag" by entering the reissue application number in an Office-wide computer grouping before a docketing transaction will be accepted. By having to set this first flag, the *>SPRE/QAS< is made aware of the assignment of the reissue application to the TC and can take steps, as may be appropriate, to instruct the examiner on reissue-specific procedures before the examination process begins, as well as throughout the **>examination of< the reissue application. Second, the *>SPRE/QAS< must remove the above-described PALM "flag" before a Notice of Allowance can be generated or the PALM transaction for an issue revision can be entered, thereby ensuring that the *>SPRE/QAS< is made aware of when the reissue application is being allowed so that

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Brief of Defendant-Appellee Mylan Pharmaceuticals Inc. was electronically filed through the appellate CM/ECF system with the Clerk of the Court. I further certify that all parties required to be served have been served.

September 25, 2014

By: */s/ Douglas H. Carsten*
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CERTIFICATE OF COMPLIANCE
PURSUANT TO FED. R. APP. P. 32(a)(7)(C)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 28.1(e)(2). The brief contains 13,430 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman.

September 25, 2014

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